CHAPTER 13

QUALITY ASSURANCE

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CHAPTER 13. QUALITY ASSURANCE

Section A - Quality Assurance Plan

1. Purpose.

The Commandant and Chief, Office of Health and Safety are committed to providing the highest quality health care to Coast Guard beneficiaries. The Health Services Quality Assurance Program (QAP) described here establishes policy, prescribes procedures, and assigns responsibility for Quality Assurance (QA) activities at Coast Guard health services facilities. It is intended to function as an integral component in a Total Quality Management (TQM) system aimed at achieving patient satisfaction by using quantitative methods to continuously improve the health services program. It is essential that the QAP integrates into the Coast Guard's overall TQM concept to improve the health care delivery system at all organizational levels. The Office of Health and Safety, Maintenance and Logistics Commands, unit commanding officers, health care providers, and patients must cooperate to ensure successful implementation of the TQM concept in the health care arena.

2. Background.

Health care QA includes monitoring and evaluating performance against generally accepted medical and dental standards to improve performance. For QA activities to be successful, health care providers and managers must directly involve themselves in the on-going process of monitoring, evaluating, and reviewing records, etc., to allow effective adjustments at the local level. For many years, Coast Guard health care facilities have conducted QA activities, usually as a normal outgrowth of conforming with this Manual's directives and the consequence of Coast Guard practitioners' good medical and dental practices. However, until 1988, no attempts were made to standardize QA activities among all Coast Guard health care facilities to ensure consistently high-quality performance. Formal QA mechanisms were lacking and documentation was sketchy. Since Maintenance and Logistics Commands were established in 1987 and the Quality Assurance Branch was reorganized in 1989 in the Office of Health and Safety, a concerted effort has been made to develop a Coast Guard-wide QA program designed to address quality-of-care issues at our facilities. The program has been tailored the program to Coast Guard medical and dental practices and incrementally phased it in over an extended time period. This dynamic program continues to evolve in an ever-changing health care environment. Directives will be amend as necessary.

3. Applicability and Scope.

All Coast Guard health care facilities with medical or dental officers assigned shall have a QAP to organize efforts to achieve and document quality health care for eligible

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beneficiaries. The QAP described here contains the essential elements required at all Coast Guard facilities and assigns responsibilities for program initiatives. All active duty, reserve, and civilian health care providers treating patients at Coast Guard clinics must participate in on-going monitoring and evaluation processes designed to assess the quality and appropriateness of the services they provide.

4. QAP Objectives.

- a. <u>Communicate important QA information</u> to enable sound clinical and management decision-making at all organizational levels.
- b. Review credentials; approve privileges.
- c. <u>Establish criteria to certify clinics</u> and ensure facilities attain and sustain compliance with established standards
- d. <u>Systematically monitor health services</u> to identify opportunities to improve patient care, implement corrective actions when required.
- e. <u>Integrate, track, and analyze QA information</u> to identify significant patterns that may require additional review or intervention.
- f. <u>Identify and justify resources</u> required to maintain acceptable patient care standards.
- g. Conduct safety and infection control surveillance.
- h. <u>Identify, assess, and decrease risk to patients and staff,</u> thereby reducing liability exposure.
- i. <u>Identify educational and training requirements</u> and assure satisfactory education and training standards are established and maintained.
- j. <u>Establish and maintain adequate systems</u> to monitor and assess patient satisfaction; respond to patient and command concerns about access and quality of care.

5. Definitions.

- a. <u>Quality</u>. The desired level of performance as measured against generally accepted health care standards.
- b. <u>Quality Health Care</u>. According to the Joint Commission on Accreditation of Healthcare Organizations, quality is the prompt, well-documented, effective, efficient, and appropriate organization and delivery of care which maximizes the probability of positive outcomes and minimizes the probability of negative outcomes. Additionally, Coast Guard health care also must meet these criteria:
 - (1) Consistent with Coast Guard policies, guidance, and Medical Manual directives:
 - (2) Consonant with practices in the applicable professional community; and
 - (3) Perceived by beneficiaries as caring, competent, and effective.

- c. <u>Quality Assurance</u>. Those functions which attempt to ensure the desired level of performance by systematically documenting, monitoring, evaluating, and, where necessary, adjusting health care activities. These functions' goal is to improve clinical performance and patient care by striving to meet established high standards.
- d. <u>Professional Oversight</u>. Monitoring and evaluating services provided by Coast Guard health care personnel and non-Federal providers, including, among others, technical guidance and assistance, peer review, resource utilization review and QA site surveys conducted by Maintenance and Logistics Commands to ensure compliance with the Coast Guard Health Care QAP.
- e. <u>Governing Body</u>. The agency that has ultimate authority and responsibility for establishing policy, maintaining quality patient care, and providing organizational management and planning.
- 6. Organizational Responsibilities. See Figure 13-A-1.
 - a. Chief, Office of Health and Safety.
 - (1) Establish at all Coast Guard health care facilities a comprehensive QAP which meets industry standards such as those published by the Joint Commission on the Accreditation of Health Care Organizations or similar independent accrediting organizations (the MLC implements the QAP);
 - (2) Govern Coast Guard health care facilities, with delegated responsibilities to the Chief, Health Services Division at each facility.
 - (3) Establish and promulgate health care policy, including professional performance standards against which quality can be measured;
 - (4) Establish and promulgate productivity and staffing standards for the health services program;
 - (5) Conduct periodic Quality Assurance Meetings for Headquarters and MLC QA staffs to coordinate and implement program policy at all organizational levels;
 - (6) Review credentials and grant privileges for all Coast Guard medical and dental officers;
 - (7) Establish criteria for Coast Guard clinic certification and, based on MLC site surveys, certify those facilities meeting established standards;
 - (8) Develop and promulgate the Quality Assurance Implementation Guide; and
 - (9) Identify education and training requirements and assure satisfactory standards are established and maintained. Coordinate and fund continuing professional education for all health services personnel.
 - b. Maintenance and Logistics Commands.

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- (1) Ensure the Commandant's Health Care QA Program is executed at the field level;
- (2) Periodically conduct QA site surveys of all health services facilities in their area in accordance with Section 13.F. provisions. Based on survey findings, recommend clinic certification status to Commandant (G-WK) in accordance with Section 13.G. provisions; pay customer assistance visits when necessary;
- (3) Develop and maintain standard operating procedure manuals and/or health services support program guides necessary to provide operational guidance for clinic activities:
- (4) Develop and maintain Quality Assurance Checklists for QA site surveys;
- (5) Perform utilization review of clinic expenditures, staffing, equipment, supplies, and facilities; review and process all requests for non-Federal medical care from units in its jurisdiction; and
- (6) Provide technical and professional advice regarding health services to units, as required.

c. Commanding Officers.

- (1) Ensure the unit actively pursues health services QAP standards;
- (2) Appoint in writing an individual to serve as Health Services Quality Assurance Coordinator in accordance with Paragraph 13.A.6.e.;
- (3) Appoint health services staff members to serve on a Health Services Quality Assurance Focus Group in accordance with Paragraph 13.A.6.f.; and
- (4) Send copies of QA Focus Group meeting minutes to cognizant MLC (K).
- d. <u>Chief, Health Services Division</u>. Represents the Governing Body locally for Quality Assurance and related activities.

e. Health Services QA Coordinator.

- (1) The Health Services QA Coordinator should be a senior health services staff member with these characteristics:
 - (a) demonstrates the ability and motivation to provide and ensure quality health care:
 - (b) knows the requirements of the Medical Manual, COMDTINST M6000.1 (series);
 - (c) communicates well both in writing and orally;
 - (d) well versed in delivering Coast Guard health care and supports the goals of health care quality assurance; and
 - (e) is an E-6 or above.
- (2) The Health Care QA Coordinator fulfills these responsibilities:

- (f) Directs Health Services QA Focus Group activities;
- (g) Implements the health care QA program locally by identifying and coordinating resolution of health care QA problems;
- (h) Develops and promulgates an annual QA calendar which sets the agenda for all QA activities at the unit, including among other activities QA Focus Group meetings and all monitoring and evaluation functions; and
- (a) Other health care QA functions as necessary.
- (3) The Chief, Health Services Division or Clinic Administrator may be appointed as the Health Services QA Coordinator.. However, this is not recommended in larger clinics since these two individuals are expected to provide necessary management expertise and clinical guidance in conducting the health care QA program and effecting any required program adjustments. The Health Services QA Coordinator's relationship to the Chief, Health Services Division is advisory.

f. Health Services QA Focus Group.

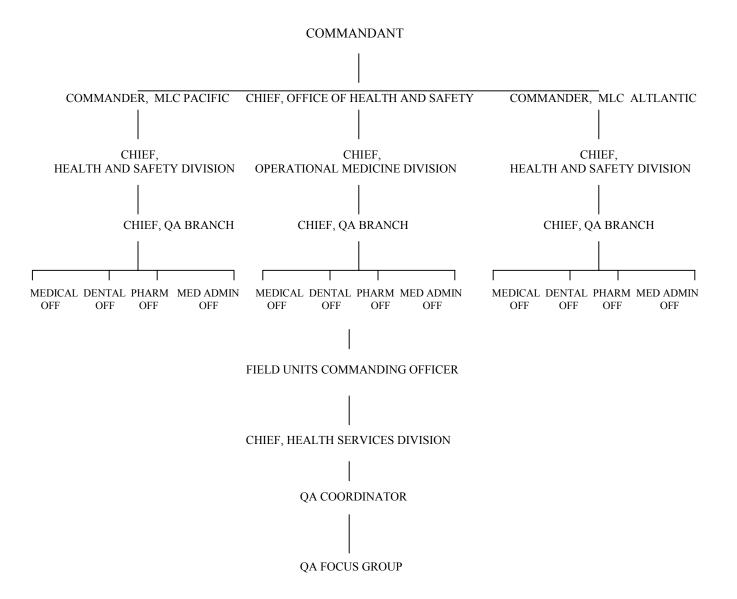
- (1) The Health Services QA Focus Group shall consist of three to 15 members, depending on unit size, including both enlisted members and officers who broadly represent the health care services provided at that unit.
- (2) Members will include at least a medical or dental officer, a clinic supervisor, and department representatives, e.g., pharmacy, physical therapy, x-ray, laboratory, etc. If desired, the Health Care QA Focus Group at small units may operate as a "Committee of the Whole" of all staff members.
- (3) The Health Services QA Focus Group advises the Chief, Health Services Division about the quality of the facility's health care and performs these functions:
 - (a) Identifies and resolves problems which affect the quality of health care delivery at the facility (The Chief Health Services Division may delegate investigating and resolving a particular QA problem to the staff member responsible for the clinical area where the problem has been identified, e.g., laboratory, patient reception, etc.).
 - (b) Ensures all required health services committee meetings are held according to the provisions of the Coast Guard Medical Manual, MLC standard operating procedures and operational guides, and local instructions, including, among others, the Pharmacy and Therapeutics Committee (see Paragraph 10.A.8.) and Patient Advisory Committee (see Paragraph 13-N-2)
 - (c) Uses existing USCG standards, MLC QA checklists, and monitoring and evaluation exercises to monitor and evaluate the quality of services delivered both in-house and by contract providers.

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- (d) Performs systematic, documented reviews of health records for compliance and adherence to Medical Manual standards and MLC standard operating procedures, health and safety support program guides, and QA checklists.
- (e) Solicits and monitors patient perceptions and satisfaction by surveys and questionnaires.
- (f) The Health Care QA Focus Group shall meet at least quarterly and more often as local needs dictate. The MTF will maintain these meetings' original minutes; forwarding copies of the minutes along with monitoring and evaluation reports through the chain of command for the cognizant MLC (K) and Commandant (G-WKH) to review.
- 7. <u>Confidentiality Statement</u>. All documents created under authority of this instruction are health services quality assurance records and part of the Coast Guard's QAP. They are confidential and privileged under 14 USC 645 provisions. Releasing health services QA documents is expressly prohibited except in limited circumstances listed in 14 USC 645.
- 8. <u>QAP Review and Evaluation</u>. The Chief, Office of Health and Safety will annually review and evaluate the QAP. The review will reappraise the QA Plan and incorporate comments from the Commanders of the Maintenance and Logistics Commands on implementation activities at field units during the preceding year.
 - a. By 30 November annually MLC Commanders shall provide to Commandant (G-WK)a written QA Review and Evaluation Report addressing these topics during the previous fiscal year:
 - (1) Summary of clinical certifications and accreditations;
 - (2) Summary of significant clinical problems identified;
 - (3) Summary of peer review activities;
 - (4) Recommended QAP modifications; and
 - (5) MLC QA Plan for upcoming calendar year.
 - b. <u>By 31 January annually</u> the <u>Chief</u>, Office of Health and Safety will issue to all units a written QA report addressing these topics:
 - (1) Summary of clinical certifications and accreditations during past fiscal year;
 - (2) Summary of significant clinical problems identified during past year;
 - (3) QAP modifications for the current fiscal year; and
 - (4) QA Plan for the current fiscal year.

FIGURE 13-A-1

ORGANIZATIONAL CHART FOR QUALITY ASSURANCE PROGRAM



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Section B – Credentials Maintenance and Review

1. <u>Background</u>. Commandant (G-WK) is responsible for ensuring health care providers in Coast Guard facilities are competent and capable. Verifying medical or dental officer qualifications is essential to assure providers are prepared for the scope of practice for which they are employed. To maintain quality health care the credentials review process must be effective. Primary sources must certify as valid certain credentials, including qualifying professional degree(s), license(s), graduate training, and references before a provider may practice independently in Coast Guard health care facilities. All candidates for USCG employment, USCG civil service employees, assigned USPHS commissioned corps officers, and contract providers who provide direct patient care in Coast Guard health care facilities will comply with this chapter's provisions as applicable. The credentials shall be reviewed for each medical or dental officer appointed to a position providing patient care. Clinical responsibilities will be assigned based on this review.

2. Definitions.

- a. <u>Contract Provider</u>. An individual physician, dentist, physician assistant or nurse practitioner, other than uniformed services personnel, who provides care in a Coast Guard health services facility under a contractual agreement with the Coast Guard.
- b. <u>Credentials</u>. Documents constituting evidence of education, clinical training, licensure, experience, clinical competence and ethical behavior.
- c. <u>Credentials Maintenance</u>. Filing, updating, modifying or completing files or documents about practitioner credentials.
- d. <u>Credentials Review</u>. The process of checking a practitioner's verified credentials and other supporting documents to evaluate potential assignments, assign or rescind clinical privileges, or take administrative or personnel actions.
- e. <u>Dental Officer</u>. A U.S. Public Health Service (USPHS) commissioned officer assigned to the Coast Guard, who is a graduate of an accredited school of dentistry and holds a valid, current state license to practice dentistry.
- f. <u>Intake Credentials Verification</u>. The process of verifying a practitioner's license, education, training, and competence before initial assignment or employment.
- g. <u>License (Current, Valid)</u>. A certificate issued by one of the 50 states, District of Columbia or U.S. Territories (Guam, Puerto Rico, Virgin Islands) that permits a person to practice medicine, dentistry, or other allied health profession.
- h. <u>Medical Officer</u>. A commissioned USCG or USPHS officer assigned to the Coast Guard who has graduated from an accredited educational institution and is currently licensed as a physician or nurse practitioner; or a physician assistant holding valid certification from the National Association on Certification of Physician Assistants.

- i. <u>Primary Source Verification</u>. Verification of a credential with an individual or institution possessing direct knowledge of the validity or authenticity of the particular credential.
- j. <u>Provider</u>. A person granted individual clinical privileges to diagnose and treat diseases and conditions, including physicians, dentists, physician assistants, nurse practitioners, podiatrists, optometrists, and clinical psychologists.

3. Pre-selection Credentials Review.

- a. <u>Commandant (G-WKH)</u> PHS liaison officer in cooperation with the PHS Division of Commissioned Personnel (DCP) shall perform a pre-employment review and verify minimum standards before appointing Commissioned personnel. The DCP also screens individuals and certain credentials as part of the commissioning process. Coast Guard procedures are designed to complement the DCP's; the Coast Guard may alter its policies as DCP modifies them.
- b. <u>The cognizant MLC or local command</u> by direction shall perform a pre-employment review of and verify Civil Service employees, contractors providing care in Coast Guard health care facilities, and students.
- c. <u>To review and verify student credentials</u>, obtain a letter from the school stating the student is in good academic standing. Document malpractice coverage arrangements through an appropriate affiliation agreement. (Student Extern Programs, COMDTINST 6400.1 (series).
- 4. <u>Practitioner Credentials File (PCF)</u>. Commandant (G-WKH-2) shall initiate and maintain PCFs for all Civil Service and Uniformed Service licensed practitioners for the entire length of their employment or service. Persons unable or unwilling to provide required information may be disqualified for employment or accession. These files must contain this information:
 - a. A current curriculum vitae accounting for all time since the qualifying degree was received.
 - b. <u>Copies of qualifying educational degrees</u> (diploma, certificate) needed to perform clinical duties with the documents' primary source verification; see Section 13-B-6.
 - c. <u>Copies of required postgraduate training certificates for the area of work;</u> for example, internship, residency, fellowship, nurse practitioner or physician assistant training, and primary source verification of these documents' authenticity.
 - d. Copies of state licenses for all states in which the practitioner is licensed (active or inactive), current renewal certificates, and Educational Commission for Foreign Medical Graduates (ECFMG) certification if the practitioner graduated from a medical school not in the Continental U. S., Hawaii, Alaska, or from a medical school not accredited by the American Association Liaison Committee on Medical Education in Puerto Rico. The practitioner must attach a statement of explanation

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- for lapsed state licenses or those subject to disciplinary action. The primary source must verify all licenses or renewal certificates.
- e. <u>Copies of specialty board and fellowship certificates</u> with primary source verification of these documents.
- f. <u>Proof of current (within one year) competence</u>, i.e., two letters of reference for initial appointment and a description of recent clinical privileges held (practitioner's supervisor must note concurrence with and approval of privilege performance).
 - (1) The official reviewing letters of reference is authorized to contact the author of the letters to verify authorship and authenticity of letters. The official is also authorized to request a second letter of reference from an author when the first letter is deemed unclear. The official reviewing a letter of reference is authorized to contact the author via telephone in cases in which the author declines to respond in writing. In such cases, the official will document in a telephone log the site, date, time, identity of call participants and a detailed description of the conversation.
- g. A statement explaining any involvement in malpractice cases and claims, including a brief review of the facts about the practitioner's involvement.
- h. A statement about any hospitals', licensing boards', or other agencies' disciplinary action.
- i. <u>A copy of current certification in Cardiopulmonary Resuscitation</u> from the American Heart Association or American Red Cross.
- j. <u>Copies of all current and prior Drug Enforcement</u> Agency (DEA) registration, as appropriate.
- k. National Practitioner Data Bank (NPDB) query.

5. <u>Documentation</u>.

- a. <u>Documents will be placed into a U. S. Coast Guard Training Record (CG-5285)</u> folder. Commandant (G-WKH-2) will maintain files in a locked cabinet. PCFs and their contents are Class III (maximum security) records and protected from disclosure under the Privacy Act. Do not release documents in the PCF to any other individual or entity unless the provider has given express written permission.
- b. Place documents in the six-section folder are as follows:
 - (1) <u>Section One</u>: Coast Guard clinical privilege documents.
 - (2) Section Two: Reference letters.
 - (3) <u>Section Three</u>: Adverse actions, malpractice documents, proof of malpractice coverage, statements about adverse information or malpractice claims.

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- (4) <u>Section Four</u>: Copies of CPR certification cards, continuing education certificates (CME), other military or civilian courses other than initial qualifying degree.
 - (a) By 31 December **every other year**, each provider shall submit a summary of CME completed during the **prior 2 years** to Commandant G-WKH-2.
 - (b) The CME summary will be in the form of a list in tabular format and will include the name of the course, date taken, sponsoring organization and CME earned.
 - (c) Providers who are members of the professional organizations that maintain transcripts can submit a transcript in lieu of a summary of CME.
- (5) <u>Section Five</u>: JCAHO-accredited hospital letter on admitting privileges, privileges granted by other or previous institutions, curriculum vitae.
- (6) Section Six: Copies of license(s), diploma(s) or degree certificates, ECFMG certificate (if applicable), Internship certificate, Residency Certificate, Fellowship documents, and Board Certification. Primary sources must verify all documents in Section Six.
- c. See Figure 13-B-1 for a list of required documents by provider category.

6. Verification.

- a. To verify education, training, licensure or registration, certification, ECFMG and board certification, obtain either an original letter from the educational institution or certifying body attesting to successful completion of specialty training, or verify by telephone call between the Coast Guard representative and educational institution or specialty board. Record telephone verification on the document itself and on official letterhead signed and dated by the person making the call. Place all verification documents with their source documents in PCF Section Six.
- b. Commandant (G-WKH) will verify uniformed services persons before appointment.
- c. <u>Before selection of Civil Service and contract providers</u>, there will be a verification of education, training, licensure, experience, certification or registration, and current competence.
- d. <u>To verify experience and current competence</u> requires at least two recommendation letters from appropriate sources as listed below. Commandant (G-WKH-2) or the appropriate MLC shall receive direct letters from the person providing the reference. Verify descriptions of recent clinical privileges as above.
 - (1) A letter either from the hospital chief of staff, clinic administrator, professional head, or department head if the individual has professional or clinical privileges or is associated with a hospital or clinic; or

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- (2) A letter from the director or a faculty member of the individual's training program if he or she has been in a training program in the previous two years; or
- (3) A letter from a practitioner in the appointee's discipline who is in a position to evaluate the appointee's peer and a professional association or society association (mandatory if the appointee is self-employed).

7. Contract Provider Credentials Review.

- a. <u>All contract providers who perform any part of their work</u> in a Coast Guard health care facility will submit credentials documents to the appropriate MLC per Paragraph 13.B.6. above and MLC SOPs.
- b. The contracting officer will verify documents.
- c. <u>At the contracting officer's request</u>, MLC (K) will perform a <u>technical</u> review of the providers' credentials.

8. Reverification.

- a. These credentials are renewable and will be primary source on renewal: License, PA certification, Board certification, and contract providers' malpractice coverage. Reverify contract providers' credentials at contract renewal.
- b. Reverify these credentials by original letter or telephone contact. The person making the call will record telephone contact on the document and by a separate, signed memorandum.

9. National Practitioner Data Bank.

- a. <u>Commandant (G-WK) possesses sole authority to report</u> to the National Practitioner Data Bank. Commandant (G-WKH-2) is designated as the appropriate entity for National Practitioner Data Bank queries. Coordinate all queries for patient care providers through this branch.
- b. A reply from the NPDB is not required before the practitioner begins providing services. However, any provider whose credential verification is not fully completed will be considered to have a conditional appointment until all credentials are verified as required.

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FIGURE 13-B-1
REQUIRED CREDENTIALS BY PROVIDER CATEGORY

| | A | В | C | D | E | F | G | Н | I | J | K |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|
| Physicians | X | X | X | X | X | X | X | X | X | X | X |
| General Practice Physicians* | X | X | X | X | | X | X | X | X | X | X |
| Dentists | X | X | X | X | | | X | X | X | X | X |
| Physician Assistants | X | X | X | X | | | X | X | X | | X |
| Nurse Practitioners | X | X | X | X | | | X | X | X | | X |
| Optometrists | X | X | | X | | | X | X | X | | X |
| Physical Therapists | X | X | X | X | | | X | X | X | | X |
| Dental Hygienists | X | X | | X | | | X | X | X | | X |

- A. Current curriculum vitae
- B. Copies of qualifying educational degrees
- C. Copies of required postgraduate training certificates for the area of work; for example, internship, residency, fellowship, nurse practitioner or physician assistant schooling
- D. Copies of state license(s)
- E. Copies of specialty board certification and fellowship certificates
- F. Proof of current competence, recent clinical privileges
- G. Proof of malpractice coverage (contractors only)
- H. Statement explaining malpractice claims, other adverse actions
- I. CPR certification
- J. DEA certification
- K. NPDB query

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^{*} General Practitioners. Physicians who have completed one year of Graduate Medical Education (Internship) and have not completed a full residency in a medical specialty.

Section C – Clinical Privileges

- 1. <u>Purpose</u>. Granting individual clinical privileges to independent practitioners providing services in health care organizations is an essential component of quality assurance. Clinical privilege granting and rescinding activities define the organization's scope of care and services available to patients. The privileging process is directed solely and specifically at providing quality patient care; it is not a disciplinary or personnel management system. However, privileging actions may accompany administrative or judicial actions or engender them. Granting and rescinding clinical privileges is highly confidential, and must be conducted according to strict rules to prevent improper or prejudiced actions. This section establishes processes and procedures to grant and rescind clinical privileges. These provisions fall outside the scope of Administrative Investigations Manual, COMDTINST M5830.1 (series).
- 2. <u>Background</u>. Commandant (G-WK) is responsible for planning, developing, and administering a comprehensive, high-quality health care program which must ensure the persons providing care have appropriate, verified licenses, education, and training. Coast Guard health care practitioners must adhere to commonly accepted standards for treatment and therapeutic modalities. In the Coast Guard, adherence to accepted standards is achieved by rigorous quality assurance (QA) and providers' peer reviews.

3. Definitions.

- a. <u>Abeyance</u>. Temporarily assigning a provider to non-clinical duties while an internal (focused) or external review or investigation is conducted.
- b. <u>Clinical Privileges</u>. Type of practice activities authorized to be performed in the facility, within defined limits, based on the providers' education, professional license as appropriate, experience, current competence, ability, judgment, and health status.
- c. <u>External Review</u>. Administrative, non-judicial, or criminal investigations initiated by entities other than the Coast Guard health services program.
- d. <u>Focused Review</u>. An internal administrative mechanism to evaluate information about clinical care or practice. Coast Guard health services officers conduct focused reviews as part of the quality assurance program.
- e. <u>Full Staff Privileges</u>. Unrestricted privileges as defined by "Clinical Privileges" above, reevaluated and renewed every two years.
- f. <u>Peer Review</u>. Review by an individual (or individuals) who possesses relevant professional knowledge or experience, usually in the same discipline as the individual under review.
- g. <u>Privileging</u>. The process through which providers are given the authority and responsibility to make independent decisions to diagnose illnesses and/or initiate, alter, or terminate a regimen of medical or dental care.

- h. <u>Professional Review Committee</u>. A committee appointed by Commandant (G-WK), composed of the Deputy Director of Health and Safety (G-WKd) and the Chiefs of the Operational Medicine Division (G-WKH), Operational and Clinical Medicine (G-WKH-1), and Quality Assurance Branch (G-WKH-2) or their designees. At least two physicians and one dentist shall be members.
- i. <u>Provider</u>. For this chapter, an individual granted clinical privileges to independently diagnose and treat diseases and conditions. Physicians, dentists, physician assistants, nurse practitioners, podiatrists, optometrists, and clinical psychologists are provider disciplines within the Coast Guard health services program.
- j. <u>Provisional Clinical Privileges</u>. Initial privileges, generally effective 365 days from issue date, Commandant (G-WK) grants providers when they begin practice in the Coast Guard health services program or earn a new or changed clinical privilege. New Coast Guard providers are eligible for full staff privileges after successfully completing one year of provisional privileges.
- k. Expiration of Credentials. It is ultimately the responsibility of the provider to ensure that all credentials required for clinical privileges are renewed prior to their expiration dates. If any credential required for clinical privileges is allowed to expire, the provider may have clinical privileges suspended or terminated. This will remove the provider from direct patient care and may also render the provider ineligible to receive any special pay for clinical duties while the provider is in this status.
- 4. <u>Applicability and Scope</u>. All military and salaried civilian, and contract civilian Coast Guard health care providers shall have clinical privileges assigned. Health services personnel (other than providers) who function under a standard job or position description or standard protocol, policies, and procedures, or who must consult with another provider before or during medical or dental treatment will not receive clinical privileges.

5. Clinical Privileges.

a. General.

(1) Commandant (G-WK) will grant clinical privileges based on education, specific training, experience, license or certification status, and current competence. He or she shall consider facility, support staff, equipment capability, etc. limitations which may prevent a provider from conducting certain activities. Commandant (G-WK) shall assign or require providers to perform professional duties *only* if their education, training, and experience qualifies them to perform such duties. Commandant (G-WK) also shall consider the provider's health status and ability to treat coworkers and patients with dignity and respect (i.e., the presence or absence of good interpersonal skills and "bedside manner") when granting privileges.

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- (2) At defined intervals the provider shall use form CG-5575, Request for Clinical Privileges, to initiate a request for clinical privileges. Chief, Health Services Division (HSD) shall recommend whether to approve or disapprove clinical privileges and submit the recommendation to Commandant (G-WK) through MLC (K). The Professional Review Committee shall review the privileges requested and recommend a response to Commandant (G-WK). The actions of the Professional Review Committee actions will not be considered final until Commandant (G-WK) approves them.
- (3) Absence of clinical privileges must not delay treatment in an emergency—a situation in which failure to provide treatment or hospitalization would result in undue suffering or endanger life or limb. In such cases the providers are expected to do everything in their power to save the patient's life or treat the condition.
- (4) On transfer, the gaining Chief, Health Services Division shall evaluate the provider's clinical privileges to determine whether to continue all previously granted privileges, or whether the facility, patient population, or other factors require adjusting privileges. If a change is indicated, the provider shall submit a revised request for privileges form as delineated below for the Professional Review Committee's review and approval.
- (5) When providers in the Coast Guard are assigned TAD, Commandant (G-WKH-2) shall transmit a copy of the provider's clinical privileges to the host SMO/SDO who will evaluate the privileges and advise the provider which if any privileges will be restricted at that site. When assigned TAD to a clinic that is accredited by JCAHO, AAAHC or other external accrediting agencies, Commandant (G-WKH-2) will also transmit a credentials transfer brief (CTB) to the host command.
- (6) When providers from DoD are assigned TAD to Coast Guard clinics, their parent command shall transmit a copy of their clinical privileges as well as a CTB to the host command prior to their arrival. The SMO/SDO will determine if any of the privileges will be restricted.

b. Procedures.

- (1) Commandant (G-WKH) will inform new Coast Guard providers they must request provisional clinical privileges in writing before accession to active duty or formal employment. New Coast Guard providers shall send written requests for provisional clinical privileges to Commandant (G-WKH) by facsimile or mail at least 45 days before accession. Privilege requests for persons already employed by or assigned to the Coast Guard shall be forwarded by mail for facsimile (FAX) to Commandant (G-WKH) through the cognizant MLC (k) for Professional Review Committee action.
- (2) Providers do not require Professional Review Committee approval before reporting for duty. Until credentials review is completed and privileges are granted, new providers may deliver care under supervision, i.e., peers shall oversee the provider's work by reviewing monthly a random sample of at least

- 5% of the provider's charts. Any problems detected during this review will be documented in writing and copies given to the provider. Providers who fail to have the deficiencies corrected in 60 days may have their privileges restricted.
- (3) Provisional clinical privileges are effective for one year. When granting provisional privileges, the risks associated with the activities for which a new provider seeks privileges and the frequency with which he or she performs the procedures shall be considered.
- (4) Privilege request documents, Professional Review Committee actions, and any other documents relating to the granting, maintaining, reviewing or rescinding clinical privileges will be maintained in the individual provider's credentials file
- (5) The Chief, HSD shall evaluate the provider's provisional privileges after one year. Providers may apply for full staff privileges after one year of successful performance.
- (6) The Professional Review Committee will evaluate full staff privileges every two years. Providers will submit written privilege requests to Commandant (G-WKH) through MLC(kqa) 90 days before privileges are due for renewal.

c. Routine Operations of the Professional Review Committee (PRC)

- (1) The Quality Assurance (QA) Division, Commandant (G-WKH-2) will have the responsibility of monitoring and administering the granting of clinical privileges for all health care workers (HCW'S) in the Health and Safety Program that require the formal granting of clinical privileges in order to perform their duties.
 - (a) Commandant (G-WKH-2) will maintain a Practitioner Credentials File (PCF) for HCW's in the CG Health and Safety Program that will be used for granting clinical privileges.
 - (b) The local QA Coordinator at each field unit will have the responsibility of maintaining a list of the expiration dates of all significant documents required to grant clinical privileges as stipulated in Section 13-B and will notify the HCW when these documents are within 90 days of expiration.
 - (c) It is ultimately the responsibility of the HCW to take appropriate actions to prevent these documents from expiring and to ensure that current documents are entered in the PCF.
 - (d) Commandant (G-WKH-2) will also monitor the expiration dates on these documents and will coordinate through the local QA coordinators.
 - (e) The Professional Review Committee (PRC) will make recommendations to Commandant (G-WK) on the granting of clinical privileges.

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- (f) The PRC will routinely review requests for clinical privileges for HCWs upon reporting to new CG duty stations and every 2 calendar years.
- (g) The PRC can also be convened by Commandant (G-WK) to review PCF's for situations other than the routine review of clinical privileges. This is described further in section 13-C-5-d.
- (2) Commandant (G-WKH-2) will conduct a preliminary review of the requests for clinical privileges as well the entire PCF'S selected to be presented before the PRC.
- (3) Commandant (G-WKH-2) will forward requests for clinical privileges as well as the PCF'S to the cognizant Program Coordinators who will evaluate the PCF'S and decide if they should be presented before the PRC or if further information or action is required before being submitted before the PRC.
- (4) After Commandant (G-WK-2) and Program Coordinators have decided which records will be presented to the PRC, Commandant (G-WKH-2) will prepare an agenda and will schedule a PRC meeting.
- (5) The PRC will included:
 - (a) Commandant (G-WKd) as President of the PRC
 - (b) At least 2 physicians
 - (c) At least 1 dentist
 - (d) At least 1 PA or NP
 - (e) 1 member of Commandant(G-WKH-2), non-voting, to act as recorder
 - (f) Other members of Commandant (G-WKH-2)
- (6) The PRC will evaluate each PCF and can recommend any of the following actions for each case:
 - (a) Grant all requested privileges.
 - (b) Revoke all current privileges or certain specific privileges.
 - (c) Restrict all current privileges or certain specific privileges.
 - (d) Suspend all current privileges or certain specific privileges.
 - (e) Hold in abeyance all current privileges or certain specific privileges.
 - (f) Monitor or supervise of performance of clinical privileges.
 - (g) Request that any decision regarding privileges be deferred until more information is submitted to the PRC.

- (h) Maintain or modify current privileges while more information is forthcoming or an investigation is being conducted.
- (i) Request a document focused review or other type of internal investigation.
- (j) Request an external review or investigation.
- (k) Other actions as dictated by circumstances.
- (7) In accordance with the terminology adopted by the National Practitioner Data Bank (NPDB) and Federal Credentialing Program (FCP), an adverse privileging action is considered to be any action that revokes, restricts or suspends current privileges for over 30 days.
- (8) The PRC will vote on each case but the decision to approve or reject a recommendation for a privileging action will be made by WKd..
- (9) The PRC will forward its recommendations for privileging actions in the minutes of the meeting to Commandant (G-WK) via: Commandant (G-WKH-2), Commandant (G-WKH), and Commandant (G-WKH), and Commandant (G-WKd)
 - (a) Commandant (G-WK) will prepare the minutes for each meeting of the PRC.
 - (b) The minutes will specific the privileging action recommended.
 - (c) In the case of a recommendation by the PRC for an adverse privileging action or any privileging action less than granting full privileges requested, the minutes will specify the reasons or justification for that recommendation.
- (10) After Commandant (G-WK) receives the minutes, Commandant (G-WK) will make a decision on how to act on the recommendations of the PRC.
 - (a) In cases where the PRC has recommended the granting of full privileges and Commandant (G-WKd) concurs, the request for Clinical Privileges will be submitted to Commandant (G-WK) for final approval.
 - (b) In cases where the PRC has recommended an adverse privileging action or a status less than the granting of all clinical privileges requested and Command (G-WK) may forward the case to General Legal Counsel, Commandant (G-LGL) for a legal opinion prior to taking action.
- (11) In cases that have been forward to Commandant (G-LGL) for a legal opinion regarding the intended privileging action, Commandant (G-WK) will have 3 working days to make the final decision on how to act after receiving the results of the legal opinion.

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- (a) Commandant (G-WK) will attempt to contact the HCW by telephone and inform about the action.
- (b) Commandant (G-WK) will forward a letter to the HCW by mail.
- (c) Commandant (G-WK) will inform the relevant MLC(k) or MLC(m) by letter.
- (d) MLC will notify the local command and the Chief, Health Services Division,
- (12) In cases where Commandant (G-WK) requests a document or focused review or investigation prior to acting on the recommendations of the PRC, MLC will have the responsibility of organizing and funding this activity and coordinating with the local command.
 - (a) The officer or team conducting the inquiry will be convened within 10 working days after MLC has received written notification from Commandant (G-WK)
 - (b) Within 5 working days after MLC has received written notification from Commandant (G-WK), the local Commanding Officer and the Chief, Health Services Division will be notified of the identity of the officer or team conducting the inquiry.
 - (c) The inquiry will be completed within 3 working days after it has been initiated.
 - (d) Before departing, the officer or team will brief the local Commanding Officer and the Chief, Health Services Division on the findings and recommendations.
 - (e) When the review or investigation has been completed, the officer or team conducting the inquiry will forward a written report of their findings and recommendations to MLC within 10 working days.
 - (f) MLC will forward the results to Commandant (G-WK) within 5 working days After receiving it.
- (13) After receiving written notification from Commandant (G-WK) of the enactment of an adverse privileging action that does not grant full privileges, if the HCW has 30 calendar days to contact Commandant (G-WK) in writing to request a hearing
- (14) After receiving written notification from Commandant (G-WK) of the enactment of an adverse privileging action or a privileging action that does not grant full privileges, if the HCW does not request a hearing within 30 calendar days, it will be presumed that the HCW accepts and will comply with the privileging action.

Commandant (G-WK) will make the decision to notify the NPDB in the case of an adverse privileging action.

- (a) The Coast Guard Health and Safety Program is considered a health care entity under the Health Care Quality Improvement Act of 1987.
 - 1 Health care entities are requires to report any adverse privileging action that is enacted for over 30 calendar days for all physicians and dentists.
 - <u>2</u> Health care entities are not required to report adverse privileging actions for other HCW'S
- (b) Commander (G-WK) will make the final decision to report adverse privileging actions
- (c) Commandant (G-WKH-2) will submit the report to the NPBD when directed by Commandant (G-WK) in accordance with current NPDB

d. Non-Routine Privileging Actions.

- (1) The objective of a non -routine privileging action is to affect a change in clinical privileging that is motivated by an urgent set of circumstances that precludes waiting for the routinely schedule evaluation for clinical privileges by the PRC.
- (2) In these cases, the local command will normally initiate a request for modification or termination of clinical privileges based on events at the local field unit level.
 - (a) The request will be in the form of a letter from the local command MLC(k).
- (3) The letter must describe in detail the exact circumstances leading up to the decision to request a modification or termination of clinical privileges.
- (4) The letter must identify the individuals who initiated the complaint or action and every member of the staff and chain of command who had any involvement in the case
 - (a) In extreme cases, the local command may elect to communicate immediately with MLC(k) by telephone. However this must be followed by the issuance of a letter
 - (b) Local commanding officers may have questions or concerns about providers and under what circumstances requests for restrictive actions should be made.
- (5) The local command should use the cognizant MLC(k) as the POC for these queries.

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- (6) Requests for information guidance can be made via telephone, electronic or written correspondence.
- (7) MLC(k) will evaluate the request from the local command and will have up to 5 working days to determine what action will be taken including:
 - (a) No action.
 - (b) Request more information from the local command.
 - (c) Immediate action such as placing the HCW in abeyance.
 - 1 Normally Commandant (G-WK) will make the decision to hold the privileges of the HCW in abeyance.
 - Incases where circumstances are extreme MLC(k) may temporarily hold the privileges in abeyance and then contact Commandant (G-WK) as soon as possible.
 - (d) Convening a document or focused review.
 - (e) Submitting the case for disposition to Commandant (G-WK).
- (8) If MLC (K) determines that a document or focused review is indicated, an officer or team will be on site within 10 working days if the decision.
 - (a) The HCW will notified of the decision as soon as possible by telephone and this will be followed by a letter from MLC (k) to the HCW describing the circumstances that led to this action.
 - (b) The local Commanding Officer and Chief, Health Service Division will be appraised of the identity of the officer or team that will be convened for the document or focused review within 5 working days after the decision to convene has been made.
 - (c) The review will be completed within 3 working days after it has been initiated.
 - (d) The officer or team will brief the local a Commanding Officer as well as the Chief, Health Services Division on the findings and recommendations.
 - (e) The officer or team will forward a written report on the findings and recommendations to MLC(k) within 10 working days after the review has been concluded.
- (9) MLC(k) will review the findings and recommendations of the document or focused review and will determine what action to take within 5 working days including:

- (a) No action.
- (b) Request more information from the local command.
- (c) Forward the written report from the document or focused review to Commandant (G-WK) for disposition with recommendations from MLC(k)
- (10) After receiving the written report if the document or focused review and the recommendations from MLC(k), Commandant (G-WK) will decide what action to take within 5 working days including:
 - (a) No action.
 - (b) Request for more information.
 - (c) Forward the report from the document or focused review with recommendations from the MLC(k) to the PRC and convene an impromptu meeting with instructions to make recommendations to Commandant (G-WK) on the issue of privileging for this particular case.
 - 1 The PRC will convene within 5 working days.
 - The PRC will vote on the case but the decision to enact a privileging action will made by WKd.
 - The PRC will forward its recommendations to Commandant (G-WK) within 3 working days.
 - (d) Summary adverse privileging action or grant less than full privileges
- (11) In the event that Commandant (G-WK) decides to enact an adverse privileging action or not grant full privileges either as a summary action or on the basis of recommendations from the PRC, the following actions will be taken by Commandant(G-WK):
 - (a) Commandant (G-WK) will attempt to contact the HCW by telephone to inform
 - (b) Commandant (G-WK) will forward a letter describing the privileging action and justification to the HCW.
 - (c) Commandant (G-WK) will forward a letter to MLC informing of the privileging action.
 - (d) MLC will forward the letter to the local command and Chief, Health Services Division.
- (12) After receiving written notification from Commandant (G-WK) of the enactment of an adverse privileging action or a privileging action that does not

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- grant full privileges, the HCW has 30 calendar days to contact Commandant (G-WK) in writing to request a hearing.
- (13) After receiving written notification from Commandant (G-WK) of the enactment of an adverse privileging action or a privileging action that does not grant full privileges, if the HCW does not request a hearing within 30 calendar days, it will be presumed that the HCW accepts and will comply with the privileging action.
- (14) Commandant (G-WK) will make the decision to notify the NPDB in the case of an adverse privileging action.
 - (a) The Coast Guard Health and Safety Program is considered a health care entity under the Health Care Quality Improvement Act of 1986.
 - 1 Health care entities are required to report any adverse privileging action that is enacted for over 30 calendar days for all physicians and dentists.
 - <u>2</u> Health care entities are not required to report adverse privileging actions for other HCW'S.
 - (b) Commandant (G-WK) will submit make the final decision to report adverse privileging actions.
 - (c) Commandant (G-WKH-2) will submit the report to the NPDB when directed by Commandant (G-WK) in accordance with current NPDB protocols.

e. Hearing Process

- (1) After receiving written notification from Commandant (G-WK) of the enactment of an adverse privileging action or a privileging action that does not grant full privileges, the HCW has 30 calendar days to contact Commandant (G-WK) in writing to request a hearing.
- (2) Commandant (G-WK) has 10 working days to convene a hearing committee after receiving request from the HCW for a hearing.
 - (a) Commandant (G-WK) will notify MLC that a hearing has been requested.
 - (b) Normally hearings will be schedule at Commandant (G-WK) unless otherwise specified.
- (3) A hearing committee will consist of at least three Coast Guard Public Health Service (CG/PHS) officers with the rank of Lieutenant Commander or above and a representative Commandant (G-LGL) to act as legal advisor. At least two of the CGPHS officers on the hearing committee will have board

specialties the same as the provider requesting the hearing. Each (CGPHS) officer will have one vote.

- (a) The HCW will bear all expenses of transporting witnesses or legal advisors.
- (b) The HCW has the right to:
- (c) Have an attorney or legal advisor present who can provide legal advice to the HCW. The legal advisor will not participate directly in the proceedings.
- (d) To record of the proceedings.
- (e) To call and cross-examine witnesses.
- (f) To present relevant written evidence.
- (g) To submit a written statement at the conclusion of the hearing.
- (4) The hearing committee will convey its findings in a written report within 3 working days after the conclusion of the hearing to Commandant (G-WK).
- (5) Commandant (G-WK) will have 3 working days to act on the findings of the hearing.
 - (a) Commandant (G-WK) will attempt to contact the HCW by telephone and inform about the results of the hearing and the action to be taken
 - (b) Commandant (G-WK) will forward a letter to the HCW by mail.
 - (c) Commandant (G-WK) will inform the relevant MLC(k) or MLC(m) by letter.
 - (d) MLC will notify the local command and Chief, Health Services Division.

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Section D - Quality Assurance Checklists.

- 1. <u>Background</u>. The MLC Health and Safety Divisions develop and maintain Quality Assurance Checklists, which detail in question-and-answer format the essential criteria against which to assess the quality of health services. These criteria are derived from primarily from the Coast Guard Medical Manual and MLC Standard Operating Procedures and Health and Safety Support Program Guide. MLC commanders will make every effort to ensure uniformity among MLC Checklists to the extent permitted by regional command policies.
- 2. <u>Usage</u>. QA Checklists will be used primarily to assess compliance with quality assurance standards, which may focus on structure, process, or outcome measures of quality care. Their design will allow clinics and sick bays to self-assess performance by answering the series of questions the checklist poses. Compliance with checklist standards will be scored on a percentage basis. Resulting scores will determine each clinic's certification status.
 - a. <u>Key Elements</u>. Because of their critical nature and importance governing quality of care, certain clinic checklist items will be designated "key elements." Complying with key elements is essential for clinic success. A high degree of conformity with key elements will be required to certify a clinic.
 - b. <u>Elements</u>. "Elements" are certain other checklist items of a less critical (but still important) nature than key elements. Required compliance for clinic certification is lower for elements than for key elements.
 - c. <u>Information Items</u>. The checklist also contains a number of questions included for informational purposes only and not scored for certification.
- 3. <u>Amendments</u>. The MLC is responsible for Checklist amendments and may amend its Checklist at any time based on policy changes, program requirements, or suggestions and recommendations from clinic personnel or Commandant (G-WK). QA checklists are "living documents" and expected to change regularly to reflect changes in clinic operations and policy. Therefore, clinics will be given updated checklist copies long before QA site surveys.

Section E – Quality Assurance Implementation Guide (QAIG)

1. <u>Background</u>. The QAIG is a series of exercises designed to assist commands to meet Health Services QA Program requirements. Serving as a guideline, the QAIG minimizes the QA program administrative requirements by providing direction and, in many cases, templates for addressing critical QA issues. The exercises often eliminate the need for each clinic to develop its own policies and procedures by providing generic frameworks clinics can adapt to local conditions. In some cases, clinics may be required to submit evidence of completing an exercise to the MLC Health and Safety Division for data evaluation purposes.

2. Responsibilities.

- a. <u>COMMANDANT (G-WKH)</u> develops as many as 10 exercises per year on critical QA issues for inclusion in the QAIG. The MLCs distribute the exercises.
- b. <u>COMMANDER, MLC (K)</u> ensures exercises are distributed to appropriate commands for clinic personnel to complete and also reviews each facility's QAIG during quality assurance site surveys.
- c. <u>Unit QA Coordinators</u> ensure staff promptly complete all QAIG exercises and maintain a complete, up-to-date QAIG.

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Section F- Quality Assurance Site Survey.

- 1. Procedures. All Coast Guard health care facilities are subject to periodic QA site surveys designed to assess compliance with QA checklist elements, and in the case of clinics, to attain Commandant (G-WK) certification; see Section 13-G. MLC Health and Safety Divisions conduct clinic site surveys in accordance with Coast Guard Clinic Certification Program requirements. MLCs survey independent duty sick bays according to schedules promulgated by the MLC. Facilities will be given notice at least eight weeks before the scheduled survey date regarding survey format and schedule and include with the notice the current QA Checklist against which performance is to be evaluated. MLCs will make every effort to schedule QA site surveys during time periods that allow maximum clinic staff participation.
- 2. <u>Survey Format</u>. The MLC site survey team will conduct all surveys according to this format:
 - a. On arrival brief the Commanding Officer.
 - b. Review on-site clinic or sick-bay procedures and spaces according to QA checklist.
 - c. Health Records Review.
 - (1) Review selected records for documentation as required by QA checklist and verify accuracy of clinic data collection.
 - (2) Review selected records for pertinent diagnosis and care (see Section 13.I., Peer Review).
 - d. Review clinical monitoring and evaluation program.
 - e. <u>Clinic All-Hands Meeting to review the QA site survey team's preliminary findings</u> and solicit clinic <u>staff's</u> suggestions and recommendations for improvement. Feedback from the staff is encouraged on the Quality Assurance Program and the staff may present problems for troubleshooting with MLC QA Staff. A training component focusing on Quality Assurance and its incorporation into the Coast Guard's total quality management philosophy may be included
 - f. <u>Clinical services review with branch heads</u> (e.g., medical services, dental services, pharmacy, etc.).
 - g. <u>Brief Senior Medical Officer</u>, <u>Senior Dental Officer</u>, and Medical Administrative Officer.
 - h. Brief Commanding Officer.
- 3. <u>Survey Report</u>. Commander, MLC (k) will provide a written QA site survey report to the Commanding Officer within six weeks after the completed survey. Clinics which are determined to be performing at a level below that required for certification will receive the survey report or interim action report within two weeks of the site survey and will be re-survey within 180 days according to Section 13-G provisions. The report will consist

of an executive summary of major survey findings, an itemized account of facility performance measured against QA checklist elements, corrective actions required, and for clinics, certification status based on parameters described in the clinic certification program in Section 13-G. Commanding Officers must provide a written plan for corrective action to Commander, MLC (k), within 45 days of receiving the written evaluation. MLC (k) personnel will be available to assist all facilities in meeting program requirements.

4. <u>Customer Assistance Visits</u>. Customer assistance visits are interim, abbreviated visits by MLC (kqa) staff members. Units may request or MLC (k) initiate them to review compliance with applicable clinic regulations and offer assistance in meeting regulatory requirements.

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Section G - Coast Guard Clinic Certification and Accreditation

1. Clinic Certification Program.

a. <u>Background</u>. Commandant (G-WK) must certify all Coast Guard clinics with assigned medical and dental officers to provide health services. Clinic certification is based on complying with standards set forth in the Medical Manual, COMDTINST M6000.1 (series), and MLC Quality Assurance (QA) Checklists. Commandant (G-WK) certifies facilities based on the results of Quality Assurance site surveys conducted by Maintenance and Logistics Commands.

b. Responsibility.

- (1) Unit. The unit commanding officer is responsible for ensuring the command's health care facility complies with standards set forth in the Coast Guard Medical Manual and MLC QA Checklists and for meeting the minimum requirements set forth for clinic certification.
- (2) Maintenance and Logistics Command. Chief, Health and Safety Division is responsible for developing and coordinating QA Checklists and periodically conducting Quality Assurance Site Surveys at facilities in their area of responsibility. These surveys will assess compliance with existing directives and recommend the facility's certification status based on survey results.
- (3) Headquarters. Chief, Office of Health and Safety coordinates and directs the certification program, issues certificates to certified clinics, adjudicates appeals, and promulgates appropriate standards governing Coast Guard providers' delivery of health care and policies on managing and operating Coast Guard health care facilities.

c. Certification Standards.

- (1) Certified. Commandant (G-WK) will certify clinics complying with at least 90% of both key elements and all other elements on the QA Checklist. Clinics must earn re-certification every three years.
- (2) Provisionally Certified. Commandant (G-WK) will provisionally certify clinics complying with at least 80% of key elements and at least 80% of all other elements on the QA Checklist. MLC Health and Safety Divisions will annually re-survey provisionally certified facilities until they attain full certification.
- (3) Not Certified. A facility failing to achieve either certification or provisional certification under this Section's provisions will be subject to a follow-up MLC QA site survey within 180 days after notice of non-certification. During this remedial period, the MLC will assist the facility to promptly address QA survey discrepancies and may impose restrictions limiting the scope of services the facility can provide. The facility must request a follow-up survey during this period. If the facility does not receive at least provisional certification

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- (4) MLC will notify the Commanding Officer the health care facility is not certified by letter through the chain of command and detail appropriate specific restrictions on care delivery in that facility.
 - (a) The Commanding Officer shall submit weekly message reports of progress attained in eliminating disqualifying discrepancies to the cognizant MLC (k), with an information copy to Commandant (G-WKH), through the chain of command.
- d. Notice of Certification Status. The Maintenance and Logistics Command will send each surveyed facility a copy of the survey report and recommendations for corrective action within 6 weeks of the site survey. If a facility is not certified, the MLC(k) will send the survey report or an interim action report within two weeks of the site survey. Certified and provisionally certified facilities will receive certificates which they are to display prominently within.
- e. <u>Appeal of Certification Status</u>. A Unit Commanding Officer (CO) may appeal the certification status awarded as a result of the MLC Quality Assurance site survey within 30 days of the site survey report date. The Commanding Officer appeals in writing to Commandant (G-WK) through the chain of command; the appeal must specify the particular disputed QA checklist elements and reasons for the appeal. The CO must not base the appeal on corrective actions taken after the QA site survey or local misinterpretation of QA checklist elements or Medical Manual guidelines. Commandant (G-WK) will consider the appeal and render a final verdict on certification status within 30 days of receiving the appeal.

2. Clinic Accreditation Program.

- a. All Coast Guard-certified health care facilities with four or more medical officers assigned are expected to pursue accreditation from an external accrediting organization such as the Joint Commission on Accreditation of Health Care Organizations. The cognizant MLC and G-WKH must approve pursuit of this accreditation. Once a clinic achieves full or provisional external accreditation, that facility will automatically receive Coast Guard certification and be required to maintain external accreditation. A non-scored MLC QA survey will also be performed to ensure compliance with Coast Guard regulations and compliance with G-WK quality assurance program standards.
- b. The respective Maintenance and Logistics Command will provide any technical and professional assistance the health care facility requires to prepare for external accreditation. On the command's letter request, Commandant G-WK will provide funding for external accreditation surveys through the respective MLC (K).
- 3. <u>Laboratory Certification</u>. All ashore medical facilities that test human specimens to provide information to diagnose, prevent, and/or treat any disease or assess a human being's health must comply with the regulations for laboratory testing as stated in the Clinical Laboratory Improvement Amendments of 1988 (CLIA), administered by the Department of Health and Human Services.

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Section H- Monitoring and Evaluation Program

1. <u>Background</u>. Monitoring and Evaluation (M&E) is an on-going program that examines important areas of clinical care and assesses how well the facility provides that care. The Joint Commission of the Accreditation of Health Care Organizations describes M&E as the "heart" of quality assurance, a process of continuously seeking areas of potential improvement in the health care delivery system. Participants identify areas of care needing improvement, implement actions to improve care, and continually monitor these areas to ensure the improvements are effective and the quality of care satisfactory.

2. Responsibilities.

- a. Commandant (G-WKH-2) will monitor and update the M&E program as appropriate.
- b. <u>Commander, Maintenance and Logistics Commands (k)</u> shall review each facility's M&E log during Quality Assurance site surveys.
- c. <u>Unit QA Coordinators</u> shall ensure the Quality Assurance Focus Group (QAFG) performs on-going M&E according to schedule. They shall retain logs or their equivalent on file for three years for MLC QA site survey teams to review.
- 3. <u>Implementation</u>. The Monitoring and Evaluation Report Form (Figures 13-H-2 through 13-H-31) is the basic instrument documenting Coast Guard clinics' M&E. Each clinic will complete a separate form for each aspect of care monitored. M&E Reports and the M&E Data Collection Log, CG-5544 (Figure 13-H-32), are the only forms required to document M&E activity.
- 4. Using the Monitoring and Evaluation Schedule and Clinical Aspects of Care Listing.
 - a. Monitoring. M&E exercises for each category—medical (MED), dental (DEN) and drug utilization review (DUR)—are numbered, e.g., MED-1 to MED-9. Units may select any appropriate exercise from the designated category each quarter; choose optional exercises from any category, or develop their own exercises to address unit-specific issues. Units must record exercises they developed on Figures 13-H-30 and 13-H-31 and obtain cognizant MLC (k) approval. All selected exercises must address high-risk, high-volume, or problem-prone clinic procedures.
 - b. <u>Submit M&E Reports</u> to the QAFG prior to the last work day of each quarter. Therefore, start collecting data for each exercise at the beginning of each quarter.
 - c. <u>Follow-Up</u> Reports.
 - (1) <u>Studies Meeting Thresholds</u>. The facility must follow up each initial M&E Report in 6 months with a follow-up report (Figure 13-H-31).
 - (2) <u>Studies Not Meeting Thresholds</u>. The facility must produce a follow-up report 3 months after the initial report, and every 3 months thereafter until it meets that threshold(s).

- d. <u>Use the M&E Data Collection Log, CG-5544</u> (Figure 13-H-32), to evaluate health records or other information sources for compliance with the indicator criteria. Record each record reviewed as meeting or not meeting the indicator. Retain completed logs on file for three years for MLC QA site survey teams to review.
- 5. <u>Monitoring and Evaluation Report Forms</u> (Figure 13-H-2 through 31). M&E report forms contain ten (10) sections: Sections 1 through 7 on the front (Figures 13-H-2 through 30) and Sections 8 through 10 on the back (figure 13-H-31).
 - a. <u>Aspect of Care (Section 1)</u>. If the M&E program is to be meaningful, it must focus on clinical issues that have the greatest potential to affect our patients: high-volume, high-risk, or problem-prone aspects of care.
 - b. <u>Clinical Indicator (Section 2)</u>. A component of care which shall be measured to determine compliance with standards. Commandant (G-WKH-2) establishes clinical indicators with suggestions from MLCs (k) and the professional staff at all clinics.
 - c. <u>Thresholds for Evaluation (Section 3)</u>. Evaluate compliance with indicator criteria. If the evaluation does not meet a threshold, then the QAFG or its designee(s) must investigate the aspects of care and recommend specific action(s) for improvement.
 - d. <u>Data Collection Methodology (Section 4)</u>. M&E exercises' data collection processes are designed to be simple. Any staff member can collect the data. One method is to review clinical records for specific indicator criteria, which are assessed as either "met" or "not met" and recorded accordingly. The "not met" column on the Data Collection Log allows the data collector to identify the specific unmet criteria, so follow-up action can be started.
 - e. <u>Evaluation Report (Section 5)</u>. Calculate the percentage of reviewed cases that meet and do not meet the indicator criteria and enter results
 - f. Recommended Action (Section 7). The QAFG must act on completed M&E Reports. If the M&E does not meet a threshold, its QAFG must recommend action(s) to improve this aspect of care.
 - g. <u>Follow-Up Reports (Sections 8-10)</u>. Generate either 3 or 6 months after the initial report by completing Section 8 on the M&E Report Form reverse. If possible, the same person responsible for the initial report should prepare the follow-up report. In some cases, a clinic may need to continue a quarterly M&E of a particular aspect of care indefinitely. Use Form Sections 9 and 10 for this purpose.
 - h. Figure 13-H-33 depicts an M&E flow chart.

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Figure 13-H-1

| ANNUAL MONITORING AND EVALUATION SCHEDULE | | | | |
|---|-----------------|-----------------|-----|-----------------|
| QUARTER | 1 st | 2 nd | 3rd | 4 th |
| INITIAL | MED | DENT | DUR | OPTIONAL |
| *FOLLOW-UP | DUR | OPTIONAL | MED | DENT |

| CLINICAL ASPI | ECTS OF CARE FOR MONITORING AND EVALUATION |
|---------------|---|
| MED | Strep Throat Urinary Tract Infection Gastroenteritis Hypertension Non-specific Vaginitis Otitis Externa Preventive Health Activities (Healthy Lifestyle Assessment) Diagnosis of Acute Minor Illness: Acute Contact Dermatitis Diagnosis of Acute Minor Illness: Herpes Zoster (Shingles) |
| DENT | 1. Exodontia Informed Consent 2. Annual Dental Examinations 3. Dental Emergencies 4. Post-operative Infections 5. Restoration Replacements 6. Biopsies 7. Cast Restorations 8. Dental Radiographs 9. Endodontics 10. Dental Radiology 11. Periodontics |
| DUR | NSAID Therapy Antibiotic Therapy Antihistamine Therapy Antilipemic Therapy Intranasal Steroid Therapy Oral Contraceptive Therapy Smoking Cessation Aids Oral Histamine H₂ Antagonists |

Figure 13-H-1 (continued)

USING THE MONITORING AND EVALUATION SCHEDULE AND CLINICAL ASPECTS OF CARE LISTING

Each clinic shall monitor at least **one** clinical aspect of care each quarter. The schedule above determines the required category examined in each quarter. Clinics shall select an aspect of care from the menu below the specified category. For example, each year in the first quarter, M&E must be performed for a Medical (MED) aspect of care on the category menu (e.g., Strep Throat).

Submit completed M&E reports to the Quality Assurance Focus Group (QAFG) before the last work day of each quarter. Data collection for each exercise should begin on the first day of each quarter to allow time to collect and evaluate a representative data sample before the end of the quarter. It is recommended that the QAFG assign responsibility for each exercise before the start of each quarter, so that person may collect data promptly. Whenever possible, the same person responsible for the initial M&E report also should generate follow-up reports.

FOLLOW-UP REPORTS

For studies that meet thresholds:

Each initial M&E report must be followed six months later by a follow-up report.

For studies that do not meet thresholds:

A follow-up report is required three months after the initial report and every three months after that, until the evaluation meets thresholds.

Record follow-up reports on the M&E Report Form reverse in Sections 8, 9, and 10.

USING THE M&E DATA COLLECTION LOG, CG-5544

Use this form or a locally produced equivalent to evaluate health records or other information sources for compliance with the indicator criteria. Record each health record reviewed as meeting or not meeting the indicator. M&E Report Section 2 lists indicator criteria, signify unmet indicator criteria by marking the log's appropriate column (e.g., (a), (b), etc.).

Retain completed logs or equivalent on file for three years for MLC QA site survey teams' review.

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MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|---|
| 1. Aspect of Care | Diagnosis of acute minor illnesses: Strep throat. |
| 2. Indicator | All patients diagnosed with strep throat have these documents in their health record (SF-600) (record must meet all three criteria): |
| | a. A positive either throat culture or "Rapid Strep;" or a documented history of two of these three findings: Fever, purulent tonsils, or lympadenophathy; and |
| | b. A temperature was taken and recorded; and |
| | c. A description of the condition of the tonsils and/or oropharynx |
| 3. Threshold | 90% of the records reviewed shall meet the criteria contained in the indicator. |
| 4. Data Collection Methodology | a. Use CLAMS and/or a review of patient records and/or a review of lab records to retrospectively identify all patients with a diagnosis of "strep throat," up to a maximum random sample size of 25 patients. |
| | b. The QAFG or its designee will review all identified patients' health records to determine whether they meet the indicator criteria. Record the result on the M&E Data Log for each case before reporting results in Section 5. |
| | c. If the records do not meet the threshold, the QAFG shall review all cases which do not meet the criteria before recommending improvement in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
| | Signature Date |

Continued on Reverse

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|---|
| 1. Aspect of Care | Diagnosis of acute minor illnesses: Urinary Tract Infection. |
| 2. Indicator | All patients diagnosed with Urinary Tract Infection must have these documents in their health record (SF-600) (record must meet all three criteria): |
| | a. Temperature recorded, |
| | b. Documented exam (positive or negative) for cva/flank tenderness; and |
| | c. Urinalysis results. |
| 3. Threshold | 90% of the records reviewed shall meet the criteria contained in the indicator. |
| 4. Data Collection Methodology | a. Use CLAMS and/or a review of patient records and/or a review of lab records to retrospectively identify all patients with a diagnosis of "urinary tract infection," up to a maximum random sample size of 25 patients. |
| | b. The QAFG or its designee will review all identified patients' health records to determine whether they meet the indicator criteria. Record the result on the M&E Data Log for each case before reporting results in Section 5. |
| | c. If the records do not meet the threshold, the QAFG shall review all cases which do not meet the criteria before recommending improvement in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
| | Signature Date |

Continued on Reverse

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MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|---|
| 1. Aspect of Care | Diagnosis of acute minor illnesses: Acute Gastroenteritis. |
| 2. Indicator | All patients diagnosed with Acute Gastroenteritis must have these documents in their health record (SF-600) (record must meet all five criteria): |
| | a. History (presence or absence) of nausea or vomiting, and/or diarrhea (if present, number of stools in past 24 hours, b. Temperature recorded, c. History (positive or negative) of blood in stools. d. Abdominal exam, and e. Current weight of children 11 and younger. |
| 3. Threshold | 90% of the records reviewed shall meet the criteria contained in the indicator. |
| 4. Data Collection Methodology | a. Use CLAMS and/or a review of patient records and/or a review of lab records to retrospectively identify all patients with a diagnosis of "acute gastroenteritis," up to a maximum random sample size of 25 patients. |
| | b. The QAFG or its designee will review all identified patients' health records to determine whether they meet the indicator criteria. Record the result on the M&E Data Log for each case before reporting results in Section 5. |
| | c. If the records do not meet the threshold, the QAFG shall review all cases which do not meet the criteria before recommending improvement in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
| | Signature Date |

Continued on Reverse

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|---|
| 1. Aspect of Care | Out-patient management of chronic illnesses: Hypertension. |
| 2. Indicator | All patients diagnosed as hypertensive must have these documents in their health record (SF-600) (record must meet all four criteria): |
| | a. A treatment plan as evidenced in a "SOAP" entry on the SF-600, |
| | b. Blood pressure recorded at least once in preceding six months, |
| | c. Documented evaluation of EKG, electrolytes, BUN or creatinine, and |
| | d. A recommended follow-up visit. |
| 3. Threshold | 90% of the records reviewed shall meet the criteria contained in the indicator. |
| 4. Data Collection Methodology | a. Use CLAMS or a review of the hypertensive prescription files to retrospectively identify all patients diagnosed as hypertensive during a sixmonth period which begins one year before the date the M&E exercise begins |
| | b. The QAFG or its designee will review all identified patients' health records to determine whether they meet the indicator criteria. Record the result on the M&E Data Log for each case before reporting results in Section 5. |
| | c. If the records do not meet the threshold, the QAFG shall review all cases which do not meet the criteria before recommending improvement in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
| | / |
| | Signature Date |

Continued on Reverse

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MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|--|
| 1. Aspect of Care | Diagnosis of acute minor illnesses: Non-specific Vaginitis. |
| 2. Indicator | All patients diagnosed with Non-specific Vaginitis must have these documents in their health record (SF-600) (record must meet five out of six criteria): a. History of present illness, including sexual behavior; b. Past medical history; c. Medication history; d. Temperature recorded; e. Documented pelvic examination (positive or negative), including description of vaginal discharge; and f. Microscopic examination of discharge, including KOH prep (yeast), wet prep (clue cells), and testing for chlamydia and GC. |
| 3. Threshold | 90% of the records reviewed shall meet five criteria contained in the indicator. |
| 4. Data Collection Methodology | a. Use CLAMS and/or a review of patient records and/or a review of lab records to retrospectively identify all patients with a diagnosis of "non-specific vaginitis," up to a maximum random sample size of 25 patients. b. The QAFG or its designee will review all identified patients' health records to determine whether they meet the indicator criteria. Record the result on the M&E Data Log for each case before reporting results in Section 5. c. If the records do not meet the threshold, the QAFG shall review all cases which do not meet the criteria before recommending improvement in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | / |

Continued on Reverse

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|---|
| 1. Aspect of Care | Diagnosis of Acute External Otitis (Otitis Externa) |
| 2. Indicator | All patients diagnosed with Acute External Otitis must have these documents in their health record (SF-600) (record must meet three out of four criteria): a. History of present illness; b. Past medical history; c. Temperature recorded; d. Physical examination of the external ear, including: 1. Movement of the tragus or auricle to elicit pain;. 2. Description of the external ear canal, and 3. Description of any discharge found in the canal or external ear. |
| 3. Threshold | 90% of the records reviewed shall meet three criteria contained in the indicator. |
| 4. Data Collection Methodology | a. Use CLAMS and/or a review of patient records and/or a review of lab records to retrospectively identify all patients with a diagnosis of "Acute External Otitis," up to a maximum random sample size of 25 patients. b. The QAFG or its designee will review all identified patients' health records to determine whether they meet the indicator criteria. Record the result on the M&E Data Log for each case before reporting results in Section 5. c. If the records do not meet the threshold, the QAFG shall review all cases which do not meet the criteria before recommending improvement in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | / |

Continued on Reverse

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MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|---|
| 1. Aspect of Care | Preventive Health Activities (Healthy Lifestyle Assessment) |
| 2. Indicator | Adult patients' health records should assess annually these factors with health education and counseling as needed:: a. Diet; b. Tobacco use (cigarettes, smokeless tobacco, pipes, cigars); c. Alcohol use; d. Seat belt use; e. Exercise type and frequency; f. Stress identification and reduction; g. TSE/BSE; and h. Immunizations. |
| 3. Threshold | 60% of the random sample of patients seen in the study time frame should have had a health assessment performed. |
| 4. Data Collection Methodology | a. Use CLAMS or the patient appointment log to identify a random selection of adult patients who present for non-emergent conditions and/or physical exams during the study time frame. b. The QAFG or its designee will review all identified patients' health records to determine whether they meet the indicator criteria. Record the result on the M&E Data Log for each case before reporting results in Section 5. c. If the records do not meet the threshold, the QAFG shall review all cases which do not meet the criteria before recommending improvement in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | /Signature Date |

Continued on Reverse

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|---|
| 1. Aspect of Care | Diagnosis of acute minor illness: Acute Contact Dermatitis |
| 2. Indicator | All patients diagnosed with Contact Dermatitis must have these documents in their health record (SF-600) (record must meet all criteria) |
| | a. History of present illness, including any recent changes in habits, detergents, soaps, lotions, topical medications, and known contact substance cause; |
| | b. Problem-focused medical history; |
| | c. Physical examination, including the description and distribution of lesion(s) (rash). |
| 3. Threshold | 90% of the records reviewed shall meet all criteria contained in the indicator. |
| 4. Data Collection Methodology | a. Use CLAMS and/or a review of patient records to retrospectively identify all patients with a diagnosis of "contact dermatitis," "industrial dermatitis," or "poison ivy." Select a random sample of 25 patients. |
| | b. The QAFG or its designee will review all identified patients' health records to determine whether they meet the indicator criteria. Record the result on the M&E Data Log for each case before reporting results in Section 5. |
| | c. If the records do not meet the threshold, the QAFG shall review all cases which do not meet the criteria before recommending improvement in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
| | / |
| | Signature Date |

Continued on Reverse

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MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|--|
| 1. Aspect of Care | Diagnosis of acute minor illness: Herpes Zoster (Shingles) |
| 2. Indicator | All patients diagnosed with herpes zoster or shingles must have these documents in their health record (SF-600): |
| | a. History of present illness, including: 1. Course of illness and constitutional symptoms, if any, such as low grade temperature and malaise; and 2. 2 subjective complaints, such as pain; |
| | b. Problem-focused medical history; |
| | c. Temperature recorded; |
| | d. Physical examination, including these symptoms: 1. Description and distribution of primary lesions; and 2. Description and distribution of secondary lesions (if present). |
| 3. Threshold | 90% of the records reviewed shall meet all criteria contained in the indicator. |
| 4. Data Collection Methodology | a. Use CLAMS and/or a review of patient records to retrospectively identify all patients with diagnoses including "herpes zoster," "herpes," or "shingles." Select a random sample of 25 patients. |
| | b. The QAFG or its designee will review all identified patients' health records to determine whether they meet the indicator criteria. Record the result on the M&E Data Log for each case before reporting results in Section 5. |
| | c. If the records do not meet the threshold, the QAFG shall review all cases which do not meet the criteria before recommending improvement in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
| | Signature Date |
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Continued on Reverse

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|---|
| 1. Aspect of Care | Patient Education: Informed Consent for Dental Procedures. |
| 2. Indicator | The dental record documents informed consent before all exodontia procedures, evidenced by the presence of a dated informed consent document (e.g., SF-522) describing the procedure, associated risks, and alternatives; the dentist, a witness, and the patient have signed the form. |
| 3. Threshold | 100% of the records reviewed shall meet the indicator criteria. |
| 4. Data Collection Methodology | a. Use CLAMS and/or a review of patient records to retrospectively identify all patients who have undergone exodontia procedures, up to a maximum random sample of 25 patients. |
| | b. The QAFG or its designee will review all identified patients' health records to determine whether they meet the indicator criteria. Record the result on the M&E Data Log for each case before reporting results in Section 5. |
| | c. If the records do not meet the threshold, the QAFG shall review all cases which do not meet the criteria before recommending improvement in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
| | Signature Date |

Continued on Reverse

13-45 CH 13

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|--|
| 1. Aspect of Care | Preventive Dentistry: Annual Type II Dental Examination for Active Duty USCG Personnel. |
| 2. Indicator | Active duty USCG members' dental record (SF-603) contains documentation of a Type II dental examination within the past 12 months. |
| 3. Threshold | 90% of the records reviewed shall meet the indicator criteria. |
| 4. Data Collection Methodology | a. The QAFG or its designee will randomly select 50 active duty members' dental records. |
| | b. The QAFG or its designee will review each record (SF-603) to determine whether a dental officer performed a documented Type II dental examination during the past 12 months. Record the result on the M&E Data Log for each case before reporting results in Section 5. |
| | c. If the records do not meet the threshold, the QAFG shall review all cases which do not meet the criteria before recommending improvement in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
| | Signature Date |

Continued on Reverse

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|---|
| 1. Aspect of Care | Treatment of Dental Emergencies |
| 2. Indicator | Patients treated for dental emergencies make unscheduled return visits with the same complaint within 72 hours of the original sick call visit. |
| 3. Threshold | 90% of the patients seen for a dental emergency or sick call visit do <i>NOT</i> return for an <i>unscheduled</i> visit for the same complaint within 72 hours |
| 4. Data Collection Methodology | a. Maintain a daily log of all patients reporting to the clinic for dental emergencies or sick call during a 60-day period. Be sure each patient is logged and note the date. |
| - OS | b. After this 60-day period, the QAFG or its designee will review the emergency or sick call log and screen the records of all emergencies or sick call visits to identify any patients paying a return visit for the same complaint within 72 hours of the first visit. The QAFG or its designee will review these records to determine whether they meet the indicator criteria. Record the result on the M&E Data Log for each case before reporting results in Section 5. |
| | c. If the records do not meet the threshold, the QAFG shall review all cases which do not meet the criteria before recommending improvement in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | / |
| | Signature Date |

Continued on Reverse

13-47 CH 13

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|-------------------------|--|
| 1. Aspect of Care | Post-Operative Infections |
| 2. Indicator | Note surgical sites that develop infections after oral surgery on SF-603/603A and on CLAMS forms with an audit code. Post-operative inflections display these characteristics: |
| | a. Elevated oral temperature (>100° F.) in the absence of other disease; and |
| | b. Increase in purulent drainage from the surgical site; and |
| | c. Increased inflammatory signs and symptoms. |
| 3. Threshold | Fewer than 10% of the surgical site(s) will develop post-operative infections. |
| 4. Data Collection | a. Use CLAMS or a log to determine the number of surgical procedures performed in a month to a maximum of 30 cases. |
| Methodology | b. Use a record review, a log, or a CLAMS audit code to determine the number of surgical procedures performed which resulted in post-operative infections. |
| | c. The QAFG or its designee will review these records to determine whether they exceed the threshold. |
| | d. If the records exceed the threshold, the QAFG shall review all post-operative infection and recommend action to the SDO. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
| | Signature Date |

Continued on Reverse

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|-------------------------|--|
| 1. Aspect of Care | Replacing Dental Restorations |
| 2. Indicator | Note either in a log or with a CLAMS audit code all dental restorations performed to replace a restoration that has failed within one year of placement. Characteristics of failed restorations include: |
| | a. Caries; |
| | b. Lost tooth structure, including fractures; |
| | c. Fractured or displaced restoration; and |
| | d. Open contact or margin. |
| 3. Threshold | Fewer than 10% of restorations placed will need replacing within one year. |
| 4. Data Collection | a. Use CLAMS to record the number of restorations each dental officer places in one month. |
| Methodology | b. Use a CLAMS audit code or a log to record the number of each dental officer's replacement restorations required fewer than 12 months after original placement. |
| | c. The QAFG or its designee will review these records to determine whether they exceed the threshold. |
| | d. If the records exceed the threshold, the QAFG shall review all premature that specific dental officer's restorative failures and recommend action to the SDO. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
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13-49 CH 13

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
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| 1. Aspect of Care | Biopsies |
| 2. Indicator | Biopsies are submitted properly: a. Specimens are properly prepared and shipped them according to USN SF-515 guidelines; and b. Adequate amounts of tissues are submitted. |
| 3. Threshold | Fewer than 10% of biopsies submitted have SF-515 forms returned with notes indicating inadequate tissue sampling or improper preparation and shipping |
| 4. Data Collection Methodology | a. Use CLAMS or a log to identify the number biopsy procedures performed each month, to a maximum of 10 cases. b. Perform a record review of all biopsy cases (up to 10) to determine the number of cases returned with improper samples, tissue preparation, or shipping. c. The QAFG or its designee will review these records to determine whether they exceed the threshold. d. If the records exceed the threshold, the QAFG shall review all premature that specific dental officer's restorative failures and recommend action to the SDO. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | / |

Continued on Reverse

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|--|
| 1. Aspect of Care | Cast Restorations |
| 2. Indicator | Treatment is properly planned. a. Periapical radiographs and periodontal probings are evaluated before preparing the teeth, and b. Provisional (temporary) restorations are placed. |
| 3. Threshold | More than 90% of castings show a record of recent (<6 months) evaluation of periapical radiographs and periodontal probings and more than 90% of prepared teeth show a record of a successful provisional restoration. |
| 4. Data Collection Methodology | a. Use CLAMS or a log to identify the number of castings performed each month, to a maximum of 10 cases.b. Perform a record review of all casting cases (up to 10) to determine the number without pre-operative radiographs and probings or successful provisional restorations. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | / |

Continued on Reverse

13-51 CH 13

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|-------------------------|---|
| 1. Aspect of Care | Dental Radiographs |
| 2. Indicator | Radiographs are of diagnostic quality and display these characteristics: |
| | a. Apices of subject teeth visible on PA films; |
| | b. Open interproximals on BW films; |
| | c. Films are appropriately developed and fixed; and |
| | d. Films exhibit appropriate contrast |
| 3. Threshold | More than 90% of films will display appropriate technique and development. |
| 4. Data Collection | a. Review all recent (i.e., < 1 year old) dental radiographs in 50 randomly selected records, recording the number of films with technical and developing errors. |
| Methodology | b. The QAFG or its designee will review these records to determine whether they exceed the threshold. |
| | c. If the records exceed the threshold, the QAFG shall recommend action to the SDO. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | / |
| | Signature Date |

Continued on Reverse

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|--|
| 1. Aspect of Care | Endodontics |
| 2. Indicator | Appropriate radiographs have been obtained. |
| 3. Threshold | More than 90% of cases include annotated pre- <i>and</i> post-operative radiographs. |
| 4. Data Collection Methodology | a. Identify endodontic cases with a CLAMS audit code; select 10 cases at random; review those 10 records' films; note the number of records with missing pre- or post-operative films. |
| | b. The QAFG or its designee will review these records to determine whether they exceed the threshold. |
| | c. If the records exceed the threshold, the QAFG shall recommend action to the SDO. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
| | Signature Date |

Continued on Reverse

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MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|---|
| 1. Aspect of Care | Dental Radiology |
| 2. Indicator | Radiographs are appropriately ordered and correctly interpreted. |
| 3. Threshold | Appropriate radiographs are ordered in 85% of cases and noted pertinent radiographic finds in 85% of cases. |
| 4. Data Collection Methodology | a. Select 25 dental records at random; review films and forms SF-603/603A for all 25; record the number of inappropriate orders and flawed interpretations.b. The QAFG or its designee will review these records to determine whether they exceed the threshold. |
| | c. If the records exceed the threshold, the QAFG shall recommend action to the SDO. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | Signature Date |

Continued on Reverse

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
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| 1. Aspect of Care | Periodontics |
| 2. Indicator | PSR recorded and treated appropriately. |
| 3. Threshold | More than 90% of records indicate PSRs within the last 12 months and appropriate follow-up in sextants with PSR of 3 or greater. |
| 4. Data Collection | a. Select 50 dental records at random; review forms SF-603/603A for all 50; note the number of records with absent or elevated and untreated PSRs. |
| Methodology | b. The QAFG or its designee will review these records to determine whether they exceed the threshold. |
| | c. If the records exceed the threshold, the QAFG shall recommend action to the SDO. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
| | Signature Date |

Continued on Reverse

13-55 CH 13

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|---|
| 1. Aspect of Care | Drug Utilization: Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) |
| 2. Indicator | If treated with NSAIDs other than Aspirin, Indomethacin, and Ibuprofen, adults (>18 years old) with soft tissue injuries, musculo-skeletal disorders, and dental conditions must meet these criteria: |
| | a. The patient's health record documents a history of hypersensitivity, adverse reaction, or specific contraindication to using Aspirin and either Indomethacin and Ibuprofen, <u>OR</u> |
| | b. The patient has a documented failure with Aspirin and Indomethacin and Ibuprofen when used at appropriate therapeutic dosages (see below) for the indication for which currently prescribed, <u>OR</u> |
| | c. The record documents a specialist prescribed or recommended the NSAID. |
| | Therapeutic Dosage Ranges Aspirin 325-650 mg every four hours Indomethacin Up to 150 mg/day Ibuprofen Up to 3.2 gram/day, divided doses |
| 3. Threshold | 90% of cases of records reviewed meet one of the criteria contained in the |
| | indicator. |
| 4. Data Collection Methodology | a. Use CLAMS or review prescription files to retrospectively identify all patients receiving NSAIDs prescriptions except Aspirin, Indomethacin, and Ibuprofen during a one-month period. Then use CLAMS or review these records to identify patients who received the NSAIDs for the indicated conditions. b. The QAFG or its designee will review these records to determine whether they meet the criteria in the indicator. Record the result on the M&E Data Log for each case before reporting results in Section 5. c. If the records exceed the threshold, the QAFG or its designee shall review all cases which do not meet the criteria and recommend action in Section 7. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
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Continued on Reverse

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
|--------------------------------|---|
| 1. Aspect of Care | Drug Utilization: Antibiotics |
| 2. Indicator | Health records document patients diagnosed with Otitis Media (OM) receive prescriptions from a clinic practitioner for Amoxicillin, Penicillin, or Septra <u>UNLESS</u> (record may meet any one of these criteria): |
| | a. Current episode's symptoms or signs persisted after an initial regimen of listed antibiotics at therapeutic doses, <u>OR</u> |
| | b. The diagnosis is expanded to recurrent OM (3 or more document OM episodes in the last 6 months), <u>OR</u> |
| | c. The patient has a documented allergy to Amoxicillin, Penicillin, or Septra, <u>OR</u> |
| | d. Resistant strains are so prevalent in the community using listed antibiotics is contraindicated. |
| 3. Threshold | 90% of records reviewed meet one of the four criteria in the indicator. |
| 4. Data Collection Methodology | a. Use CLAMS or keep a log book to identify all patients with a reported OM diagnosis in a one-month period. Then use CLAMS, review patient records, or audit the prescription files to retrospectively identify which patients received prescriptions for antibiotics other than the three listed. |
| | b. The QAFG or its designee (e.g., Pharmacy and Therapeutics Committee) will review these patients' records to determine whether they meet the criteria in the indicator. Record the result on the M&E Data Log for each case before reporting results in Section 5. |
| | c. If the records exceed the threshold, the QAFG shall review all cases which do not meet the criteria before recommending corrective action. |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
| 7. Recommended Action | |
| | Signature Date |

Continued on Reverse

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MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator | | |
|--------------------------------|---|--|--|
| 1. Aspect of Care | Appropriate use of Antihistamines: Terfenadine (Seldane) and Astemizole (Hismanal) | | |
| 2. Indicator | Health records document patients prescribed these products have: a. Previously documented unsuccessful trial with at least one other antihistamine or documented history of intolerance to the sedative effects of antihistamines; b. No concurrent therapy with ketoconazole and/or macrolide antibiotics (Terfenadine only), and c. No evidence of impaired hepatic function or disease (see Problem Summary List). | | |
| 3. Threshold | 95% of all records reviewed meet the indicator criteria. | | |
| 4. Data Collection Methodology | a. Use CLAMS or review the prescription files to retrospectively identify all patients receiving prescriptions for Terfenadine and/or Astemizole. b. The QAFG will review these patients' records to determine whether they meet the criteria in the indicator. Record the result on the M&E Data Log for each case before reporting results in Section 5. c. If the records exceed the threshold, QAFG or its designee shall review all cases which do not meet the criteria, evaluate, and recommend action in Section 7. | | |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria | | |
| 6. Evaluator | Name: Date Evaluated | | |
| 7. Recommended Action | / | | |

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MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator | | | |
|--------------------------------|---|--|--|--|
| 1. Aspect of Care | Antilipemic agent therapy (HMG-CoA Reductase inhibitors, Gemfibrozil) | | | |
| 2. Indicator | Patients placed on therapy with the above agents have documented hyperlipidemia confirmed by at least one of these <u>baseline</u> laboratory values: | | | |
| | a. Fasting total serum cholesterol 1240 mg/dl | | | |
| | b. Fasting serum LDL 160 mg/dl | | | |
| | c. Fasting serum HDL = 35 mg/dl | | | |
| | d. Fasting serum triglyceride levels 4 250 mg/dl | | | |
| | Note: In borderline cases, additional laboratory values should be sought before initiating drug therapy. | | | |
| 3. Threshold | 80% of all records reviewed meet the indicator criteria. | | | |
| 4. Data Collection Methodology | a. Use CLAMS to review the prescription files to retrospectively identify all patients receiving prescriptions for these medications. b. The QAFG or its designee will review these patients' records to determine whether they meet the criteria in the indicator. Record the result on the M&E Data Log for each case before reporting results in Section 5. c. If the records exceed the threshold, QAFG or its designee shall review all cases which do not meet the criteria, evaluate, and recommend action in Section 7. | | | |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria | | | |
| 6. Evaluator | Name: Date Evaluated | | | |
| 7. Recommended Action | | | | |
| | Signature Date | | | |

Continued on Reverse

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MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator | | |
|--------------------------------|---|--|--|
| 1. Aspect of Care | Appropriate use of intranasal steroids (Flunisolide, Beclomethasone, Dexamthasone, Triamcinone, etc.) in seasonal and vasomotor rhinitis | | |
| 2. Indicator | All patients prescribed these medications will have: a. Documented histories of seasonal or vasomotor rhinitis (characterized by moderate to severe symptoms lasting 4 or more weeks per episode) combined with a history of unsuccessful treatment with conventional therapy including antihistamines, decongestants, or combination product therapy, and b. Administration dosage and frequency within the product manufacturer's and FDA's approved guidelines; and c. Documented evidence instruction is provided in using these medications properly. | | |
| 3. Threshold | 95% of all records reviewed meet the indicator criteria. | | |
| 4. Data Collection Methodology | a. Use CLAMS to review the prescription files to retrospectively identify all patients receiving prescriptions for intranasal steroids. b. The QAFG or its designee will review these patients' records to determine whether they meet the criteria in the indicator. Record the result on the M&E Data Log for each case before reporting results in Section 5. c. If the records exceed the threshold, QAFG or its designee shall review all cases which do not meet the criteria, evaluate, and recommend action in Section 7. | | |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria | | |
| 6. Evaluator | Name: Date Evaluated | | |
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MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator | | |
|--------------------------------|---|--|--|
| 1. Aspect of Care | Appropriate use of oral contraceptive medications | | |
| 2. Indicator | All patients prescribed these medications will have: | | |
| | a. Documented history of physical exams within the past year including personal and family medical history, pelvic exam (including pap smear), breast exam, and vital signs, and | | |
| | b. Documented evidence of instruction in the proper use of these medications, including an explanation of side effects, missed doses, increased risk factors (smoking, etc.), and drug interactions (antibiotics, etc.). | | |
| 3. Threshold | 95% of all records reviewed meet the indicator criteria. | | |
| 4. Data Collection Methodology | a. Use CLAMS to review the prescription files to retrospectively identify all patients receiving prescriptions for oral contraceptives. b. The QAFG or its designee will review these patients' records to determine whether they meet the criteria in the indicator. Record the result on the M&E Data Log for each case before reporting results in Section 5. c. If the records exceed the threshold, QAFG or its designee shall review all cases which do not meet the criteria, evaluate, and recommend action in Section 7. | | |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria | | |
| 6. Evaluator | Name: Date Evaluated | | |
| 7. Recommended Action | /Signature Date | | |
| | Signature Date | | |

Continued on Reverse

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MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator | | |
|--------------------------------|--|--|--|
| 1. Aspect of Care | Appropriate use of smoking cessation aids (nicotine patches or gum) | | |
| 2. Indicator | All patients prescribed these medications will have: a. Documented enrollment in a recognized smoking cessation behavioral modification program advocating using nicotine products as adjunct therapy. b. Health record documentation of counseling about using this medication properly, its side effects, and the member shall not smoke while undergoing this therapy. c. Documentation therapy has been 12 or fewer weeks in duration. | | |
| 3. Threshold | 95% of all records reviewed meet the indicator criteria. | | |
| 4. Data Collection Methodology | a. Use CLAMS to review the prescription files to retrospectively identify all patients receiving prescriptions for smoking cessation aids. b. The QAFG or its designee will review these patients' records to determine whether they meet the criteria in the indicator. Record the result on the M&E Data Log for each case before reporting results in Section 5. c. If the records exceed the threshold, QAFG or its designee shall review all cases which do not meet the criteria, evaluate, and recommend action in Section 7. | | |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria | | |
| 6. Evaluator | Name: Date Evaluated | | |
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MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator | | |
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| 1. Aspect of Care | Appropriate use of oral histamine H ₂ antagonist medications (Cimetidine, Ranitidine, etc.) | | |
| 2. Indicator | All patients prescribed these medications will have: | | |
| | a. Documented diagnosis of duodenal or gastric ulcer, a hypersecretory condition, gastroesophageal reflux disease, or another appropriate indication before initiating therapy as listed in the current <i>Facts and Comparisons</i> . | | |
| | b. Documented case review within 4-6 weeks and shift to maintenance dose regimen unless active disease still is present (except reflux esophagitis). | | |
| | c. Documented monitoring of phenytoin serum levels (for cimetidine only) and prothrombin times (all warfarin patients) for patients taking these drugs. | | |
| | d. Documented counseling on lifestyle modification (smoking cessation, dietary habits). | | |
| 3. Threshold | 95% of all records reviewed meet the indicator criteria. | | |
| 4. Data Collection Methodology | a. Use CLAMS to review the prescription files to retrospectively identify all patients receiving prescriptions for oral histamine H₂ antagonist medications. b. The QAFG or its designee will review these patients' records to determine whether they meet the criteria in the indicator. Record the result on the M&E Data Log for each case before reporting results in Section 5. | | |
| | c. If the records exceed the threshold, QAFG or its designee shall review all cases which do not meet the criteria, evaluate, and recommend action in Section 7. | | |
| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria | | |
| 6. Evaluator | Name: Date Evaluated | | |
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OPTIONAL

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
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| 1. Aspect of Care | |
| 2. Indicator | |
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| 3. Threshold | |
| 4. Data Collection | |
| Methodology | |
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| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
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OPTIONAL

MONITORING AND EVALUATION REPORT

| Facility | QA Coordinator |
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| 1. Aspect of Care | |
| 2. Indicator | |
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| 3. Threshold | |
| 4. Data Collection | |
| Methodology | |
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| 5. Evaluation Report | % Meeting % Not Meeting Indicator Criteria |
| 6. Evaluator | Name: Date Evaluated |
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Figure 13-H-31

| 8. 3 to 6-Month Follow-up Report | Evaluation Criteria:Continue M&E Recommended Action: | | % Not Meeting ontinue M&E |
|---|--|--------|---------------------------|
| | Signature | Date / | |
| 9. 3 to 6-Month Follow-up Report | Evaluation Criteria:Continue M&E Recommended Action: Signature | | % Not Meeting ontinue M&E |
| 10. 3 to 6-Month Follow-up Report | Evaluation Criteria:Continue M&E Recommended Action: Signature | | % Not Meeting ontinue M&E |
| FacilityAspect of Care | | | |
| Data Collector | | Date | |

M & E DATA COLLECTION LOG

[Ed. Note: Not reviewed.]

DEPT. OF TRANSP., USCG CG 5544 (9-91) LOCAL REPRO

SECTION IPEER REVIEW PROGRAM.

[Ed. Note: Text to come.]

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SECTION J UTILIZATION REVIEW PROGRAM.

[Ed. Note: Text to come.]

Section K - <u>Infection Control Program</u> (exposure control plan).

1. <u>Background</u>.

- a. <u>A standard set of infection control strategies</u> is essential to prevent transmitting infectious diseases. Because history, physical examination, and/or readily available laboratory tests cannot identify all infected patients, use these procedures when providing health care to any patient to prevent transmitting infectious agents.
- b. Health services personnel (officers, enlisted, and civilian) and emergency medical technicians (EMTs) may be exposed to infection through direct contact, droplets, or aerosols from a wide variety of microorganisms in their patients' blood, secretions, excretions, and other body fluids. Direct contact may transmit infection by contaminated instruments (e.g.; needle sticks). Everyone has the potential to transmit infectious diseases to others. All health services personnel and emergency medical technicians must know how infectious diseases spread and take appropriate precautions.
- c. While Coast Guard health services personnel and emergency medical technicians must be seriously concerned with the risk of exposure to human immunodeficiency virus (HIV), the risk of contracting other infectious diseases, such as hepatitis B virus (HBV), is much greater. HBV infection can result in serious physical debilitation and adversely affect a practitioner's ability to provide health care. Once infected, a person also poses a potential risk to future patients as an HBV infection "carrier." Infection control practices that prevent HVB transmission also prevent HIV transmission. Since 1982 a safe, effective vaccine to prevent Hepatitis B has been available; it stimulate active immunity against HBV infection and provides over 90% protection against the virus for 7 or more years after vaccination.

2. Policy.

- a. <u>Health services personnel will adhere to infection-control principles</u>, general hygiene measures, and the Center for Disease Control and Prevention's (CDC's) "universal precautions" to prevent transmitting infectious disease between themselves and their patients.
- b. Hepatitis B vaccination is mandatory for all Coast Guard health services personnel and recommended for emergency medical technicians. Civilian administrative staff and E-8 and E-9 Health Services Technicians filling administrative positions are exempt; however, these personnel are encouraged to receive Hepatitis B vaccination. EMTs and clinic administrative personnel declining to receive HBV vaccination must sign this statement on an SF-600, and it shall be retain in the individual's health record:

I understand due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring Hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated **free** with Hepatitis B vaccine. However, I now decline Hepatitis B vaccination. I understand by declining this vaccine, I continue to risk acquiring Hepatitis B,

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- a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with Hepatitis B vaccine, I can receive the vaccination series free.
- c. <u>Emergency medical technicians will adhere to the "universal precautions" described in Chapter 13-K-3</u>.
- d. <u>Under the OSHA Blood-Borne Pathogen (BBP) Standard</u>, all health services administrative and clinical personnel are occupationally exposed. All clinics shall provide the <u>health</u> care professional responsible for vaccinating employees with Hepatitis B vaccine a copy of the OSHA BBP Standard.

3. <u>Universal Precautions</u>.

- a. Since medical history and examination cannot reliably identify all patients infected with HIV or other blood-borne pathogens, care providers must consistently use blood and body-fluid precautions with all patients, including those in emergency care settings in which the risk of blood exposure is greater and the patient's infectious status usually is unknown. CDC currently recommends the "universal blood and body-fluid precautions" approach or "universal precautions."
 - (1) All health care workers will routinely use appropriate barrier precautions to prevent skin and mucous-membrane exposure when anticipating contact with any patient's blood or other body fluids. Personnel will wear gloves to touch patients' blood and body fluids, mucous membranes, or broken skin; to handle items or surfaces soiled with blood or body fluids; and to perform venipuncture and other vascular access procedures. Personnel will change gloves after contact with each patient. Personnel will wear masks and protective eyewear or face shields during procedures likely to generate blood droplets or other body fluids to prevent exposure to oral, nasal, or optic mucous membranes. Personnel will wear gowns or aprons during procedures likely to generate blood splashes or other body fluids.
 - (2) If contaminated with blood or other body fluids, personnel immediately will wash hands and other skin surfaces thoroughly. All persons shall wash their hands after completing activities likely to expose them to BBPs and remove protective clothing before leaving the work area.
 - (3) All health care workers will take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during procedures or when cleaning used instruments, disposing of used needles, and handling sharp instruments after procedures. To prevent needle stick injuries, personnel will not by hand directly recap needles, purposely bend or break them, remove them from disposable syringes, or otherwise manipulate them. After using disposable syringes and needles, scalpel blades, and other sharp items, personnel will dispose of them by placing them in puncture-resistant containers located as close to the use area as practical. The Coast Guard does not authorize using reusable needles.

- (4) Although research has not definitively implicated saliva in HIV transmission, it is prudent to use mouthpieces, resuscitation bags, or other ventilation devices instead of mouth-to-mouth resuscitation. These devices must be available for use in areas where the need for resuscitation is predictable.
- (5) Health care workers who have exuding lesions or weeping dermatitis will not provide any direct patient care or handle patient care equipment until the condition resolves.
- (6) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas with a reasonable likelihood of occupational exposure to BBPs.
- (7) Personnel shall not keep food and drink in refrigerators, freezers, shelves, drug storage areas, or cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.
- (8) Personnel shall perform all procedures involving blood or other potentially infectious materials in a manner that prevents droplets of these substances from splashing, spraying, splattering, and generating.
- (9) Pregnant health care workers apparently do not face greater risk of contracting HIV infection than non-pregnant health care workers; however, if a health care worker develops HIV infection during pregnancy, the infant risks infection due to prenatal or perinatal transmission. Therefore, pregnant health care workers will thoroughly learn and strictly adhere to universal precautions to minimize the risk of HIV transmission.
- b. <u>Implementing universal blood and body fluid precautions for all patients</u> eliminates the need for the "Blood and Body Fluid Precautions" isolation category CDC previously recommended for patients known or suspected to be infected with bloodborne pathogens. Personnel will use isolation precautions as necessary if they diagnose or suspect associated conditions, such as infectious diarrhea or tuberculosis.
- 4. <u>Precautions for Invasive Procedures</u>. The universal blood and body fluid precautions listed above and those listed below shall be the minimum precautions for all invasive procedures, defined as surgical entry into tissues, cavities, or organs; repair of major traumatic injuries in an operating or delivery room, emergency department, or out-patient setting, including both physicians' and dentists' offices; a vaginal delivery; manipulating, cutting, or removing any oral or perioral tissues, including tooth structure, during which bleeding occurs or the potential for bleeding exists.
 - a. All health care workers who participate in invasive procedures routinely shall take appropriate barrier precautions to prevent skin and mucous membrane contact with all patients' blood and other body fluids. Personnel shall wear gloves and surgical masks for procedures that commonly generate droplets, splash blood or other body fluids, or generate bone chips, such as those using rotary dental instrumentation. Personnel shall wear gowns or aprons made of materials that provide an effective barrier during invasive procedures likely to splash blood or other body fluids. All health care workers who perform or assist in vaginal deliveries shall wear gloves and

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- gowns when handling the placenta or infant until after they remove blood and amniotic fluid from the infant's skin and during post-delivery care of the umbilical cord.
- b. <u>If a glove is torn, cut, or punctured</u>, the wearer will remove it, re-scrub, and put on a new glove as promptly as patient safety permits. The needle or instrument involved in the incident shall also be remove from the sterile field.
- 5. <u>Precautions for Medical Laboratories</u>. Blood and other body fluids from all patients will be considered infectious. To supplement the universal blood and body fluid precautions listed above, these following precautions are recommended for health care workers in clinical laboratories.
 - a. <u>All blood and body fluid specimens</u> shall be placed in a well-constructed, labeled container with a secure lid to prevent leaking during transport, taking care when collecting each specimen to avoid contaminating the container's exterior or the laboratory form accompanying the specimen.
 - b. All persons obtaining or processing blood and body fluid specimens (e.g., removing tops from vacuum tubes) shall wear gloves. Personnel shall wear masks and protective eyewear if they anticipate contact with mucous membrane with blood or body fluids, change gloves, and wash hands after completing specimen processing.
 - c. <u>For routine procedures</u> such as histologic and pathologic studies or microbiologic culturing, a biological safety cabinet is not necessary. However, personnel shall use biological safety cabinets (Class I or II) whenever performing procedures with a high potential for generating droplets, including activities such as blending, sonicating, and vigorous mixing.
 - d. <u>Use mechanical pipetting devices to manipulate all liquids in the laboratory</u>. *Never pipette by mouth*.
 - e. <u>Use needles and syringes only in situations in which no alternative exists</u>. Personnel will follow the *recommended* universal precautions to prevent needle injuries.
 - f. <u>Decontaminate laboratory work surfaces</u> with an appropriate chemical germicide after spilling blood or other body fluids and <u>c</u>ompleting work activities.
 - g. <u>Decontaminate contaminated materials</u> (including gauze pads) used in laboratory tests before reprocessing or place such materials <u>in</u> bags and dispose of them according to institutional policies for disposing of infectious waste.
 - h. <u>Decontaminate scientific equipment</u> contaminated with blood or other body fluids with an appropriate chemical germicide and clean such equipment before repairing it in the laboratory or transporting it to the manufacturer.
 - i. <u>All persons shall wash their hands</u> after completing laboratory activities and remove protective clothing before leaving the laboratory.

- 6. <u>Handling Biopsy Specimens</u>. Generally, personnel must put each specimen in a sturdy container with a secure lid to prevent leaking during transport and take care when collecting specimens to avoid contaminating the container's exterior. If the outside of the container is visibly contaminated, clean and disinfect it or place it in an impervious bag before delivery to the appropriate destination for examination
- 7. <u>Using and Caring for Sharp Instruments and Needles.</u>
 - a. <u>Personnel will consider sharp items</u> (needles, scalpel blades, dental burs, and other sharp instruments) potentially infectious and handle them with extreme care to prevent unintentional injuries.
 - b. <u>Personnel must place disposable syringes and needles, scalpel blades, anesthetic carpules and other sharp items</u> in closable, leak-proof, puncture-resistant containers. Cardboard containers are not appropriate for this purpose. To prevent unintentional needle stick injuries, personnel will not by hand directly recap disposable needles, purposefully bend or break them, remove them from disposable syringes, or otherwise manipulate them after use.
 - c. <u>If multiple injections of anesthetic or other medications from a single syringe are required</u>, personnel may use these techniques in lieu of directly recapping by hand:
 - (1) Use an approved shielding device specifically designed to recap safely (e.g., "On-Guard").
 - (2) Use the "scoop" recapping technique. Affix the empty needle sheath to a flat surface and "scoop" it onto the exposed needle. A hand does not touch the sheath until the needle is securely inside.
 - (3) Use a hemostat to recap by securing the empty sheath well away from the health care worker's hand.
 - d. All Coast Guard Health Care Units shall establish a needle stick protocol; see Section 13-K-13. If a needle stick occurs, the affected person shall report the accident to his or her immediate supervisor, who will document the incident in a memorandum to the Chief, Health Services Division or health services department head, with a copy to the affected person. The memorandum will detail the needle stick's time, date, and circumstances and any medical treatment received. The Chief, Health Services Division or health services department head shall ensure the established needle stick protocol is observed in all cases.
- 8. Infection Control Procedures for Minor Surgery Areas and Dental Operatories.
 - a. Medical History. Always obtain a thorough medical history. For dental procedures, have the patient complete a Dental Health Questionnaire, NAVMED 6600/3, as Section 4-C requires. Amplify this information by asking the patient specific questions about medications, current illnesses, hepatitis, recurrent illness, unintentional weight loss, lymphadenopathy, oral soft tissue lesions, results of last HIV test, or other infections. Completely review the individual's health record or consult with a physician if the history reveals active infection or systemic disease.

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b. <u>Using Protective Attire and Barrier Techniques</u>.

- (1) Health care workers will consider all patients' blood, saliva, and other body fluids infectious. To protect themselves and patients, personnel must always wear gloves when touching:
 - (a) blood;
 - (b) saliva;
 - (c) body fluids or secretions;
 - (d) items or surfaces contaminated by the above; and
 - (e) mucous membranes.
- (2) Further, personnel must completely treat one patient, if possible, and wash and re-glove hands before performing procedures on another patient. Repeatedly using a single pair of gloves is not allowed; such use can produce defects in the glove material which reduce its effectiveness as a barrier to microorganisms. Additionally, when gloves are torn, cut, or punctured, the wearer immediately must remove them, thoroughly wash his or her hands, and put on new gloves before completing minor surgical or dental procedures.
- (3) Personnel shall wear surgical masks and protective eyewear or a chin-length plastic face shield. Personnel shall change masks after lengthy examinations or procedures, most especially after any which produce spatter. Patient protective eyewear shall be provide during all treatment procedures likely to splash or spatter blood, saliva, gingival fluids, or foreign objects. Personnel will use rubber dams, pre-procedural mouth rinsing, high-speed evacuation, and proper patient positioning, when appropriate, to minimize droplet generation and spatter in the dental operatory.
- (4) When examining or treating any patient personnel must wear smocks, gowns, or laboratory coats. If wearing a reusable gown, personnel shall wash it using a normal laundry cycle. Personnel shall change gowns at least daily, when visibly soiled, or after any surgical procedure. All treatment team members must wear long-sleeved gowns or smocks during all surgical procedures employing rotary instrumentation.

c. Washing and Caring for Hands.

- (1) Personnel must always wash hands after removing gloves between patient treatment contacts, after touching inanimate objects blood or saliva likely has contaminated, and before leaving the minor surgery area or dental operatory because gloves knowingly or unknowingly may become perforated during use. These perforations allow bacteria to enter and multiply rapidly beneath the glove material.
- (2) Whenever possible wash hands at sinks that provide hot and cold water through a single mixing valve and preferably readily accessible to the treatment

- room or operatory. After scrubbing, rinse hands in cool water to reduce the likelihood and severity of latex reactions.
- (3) For certain routine dental procedures, such as examinations and non-surgical techniques, hand-washing with plain soap is adequate, since soap and water will remove transient microorganisms. For surgical procedures, personnel must use an antimicrobial surgical hand scrub. Clinics may need to stock non-allergenic soap for allergic individuals.
- (4) Health services personnel who have exuding lesions or weeping dermatitis must refrain from all direct patient care and handling patient-care equipment until the condition resolves.

d. <u>Sterilizing and Disinfecting Dental Hand Pieces, Ultrasonic Scalers, and Dental Units.</u>

- (1) After each use with each patient, personnel will sterilize dental hand pieces (including high-speed, low-speed components used intraorally and ultrasonic scalers) because the device may aspirate a patient's blood, saliva, or gingival fluid into the hand piece or waterline. Clinics should purchase sufficient numbers of autoclavable hand pieces to meet this requirement. Dry heat is the recommended method of sterilizing dental burs.
- (2) Because water retraction valves within dental units may aspirate infectious materials back into the hand piece and water line, check valves must be installed to reduce the risk of transferring infectious material. To physically flush out contaminants run high-speed hand pieces and discharge the water into a sink or container for 3 minutes at the beginning of each day and 30 seconds between patients. Additionally, flush high-speed hand pieces with a 1:10 hypochlorite solution for 3 minutes at the end of each week.
- (3) Disinfect all dental unit surfaces with a suitable chemical germicide between patients or cover such surfaces during use. Use impervious backed paper, aluminum foil, or clear plastic wrap to cover surfaces difficult or impossible to disinfect (e.g., light handles or x-ray tube heads). Remove the covering while gloved, discard the covering, remove used and don fresh gloves, and then recover with clean material after each patient.
- (4) Dental laboratory personnel will observe infection control protocols. They will thoroughly, carefully clean blood and saliva from material used in the mouth (e.g., impression materials, occlusal registrations), especially before polishing and grinding intra-oral devices. They will clean and disinfect contaminated materials, impressions, and intra-oral devices before handling them in the dental laboratory and before putting them in a patient's mouth. They will disinfect laboratory instruments (e.g. spatulas, knives, and wax carvers), plastic benches, chucks, handles, switches, tubing, air hoses, and lab hand pieces every day. Rubber mixing bowls require overnight immersion to disinfect. Workstations, including exposed equipment, drawers, work surfaces, and sinks, require weekly surface disinfecting. Because of the increasing variety of

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- dental materials used intra-orally, dental providers should consult with manufacturers about specific materials' stability in disinfecting procedures.
- (5) Use sterile saline or sterile water as a coolant or irrigator when performing surgical procedures involving cutting soft tissue or bone.

e. Dental Radiology Sterilization and Disinfecting Procedures.

- (1) <u>Film-Holding and –Aiming Devices</u>. When practical, heat-sterilize film-holding and –aiming devices between patients. For those items unable to withstand heat sterilization, use a chemical sterilant. Immerse for 6 to 10 hours depending on the sterilant manufacturer's instructions. If sterilization is not practical, immerse these items in chemical disinfectant between patients according to manufacturer's instructions.
- (2) <u>Panoramic Unit Bite Blocks</u>. Use disposable bite block covers between patients. If disposable covers are not available, treat bite blocks similarly to film-holding devices.
- (3) <u>Handling Intra-oral Film Packets</u>. Place intra-oral film removed from a patient's mouth directly into a disposable container such as a paper cup or towel for transfer to the darkroom. Discard wrappers directly into a refuse container or into a disposable towel to prevent contaminating the darkroom counter
- (4) <u>X-ray Chair</u>. Between patients wipe arm- and headrests with a chemical surface disinfecting solution. If using paper or plastic headrest covers, replace them after each patient.
- (5) <u>Intra-oral X-ray Tubehead and Exposure Buttons</u>. Wipe these items with a surface disinfectant or cover them after each patient visit. Do not allow disinfectant liquid to leak into the tubehead seams or the exposure button switch

9. Sterilizing and Disinfecting.

a. <u>Instrument Categories (Spaulding Classification)</u>. The Spaulding Classification defines as critical instruments that normally penetrate soft tissue, teeth, or bone (e.g., forceps, scalpels, bone chisels, scalers, surgical burs, etc.). They must be heat-sterilized after each use. Instruments not intended to penetrate soft or hard tissues (e.g., amalgam carvers, plastic instruments, etc.) but which may come into contact with tissues are semi-critical and also should be heat-sterilized after each use. If heat sterilization is not possible, semi-critical instruments must receive chemical sterilization. Non-critical instruments never contact tissue. Sterilization is recommended for non-critical instruments, but high-level disinfection is acceptable.

b. Instrument Preparation.

(6) <u>Initially Storing Contaminated Instruments</u>. Immerse contaminated instruments in a container of soapy water immediately after use or completing the patient visit.

- (7) <u>Cleansing Instruments</u>. Instruments must be cleansed for sterilization to be effective. Cleanse them using an ultrasonic cleaner according to the manufacturer's instructions. Hand-scrubbing instruments is prohibited. Persons who cleanse instruments must wear heavy-duty ("Nitrile") rubber utility gloves to reduce the risk of injury. Inspect instruments for cleanliness before preparing them for packaging.
- (8) Packaging and Wrapping Instruments. Depending on intended use, wrap or package most instruments individually or in sets. Packaging in metal or plastic trays reduces set-up time; instruments and other materials arranged systematically are more convenient. Package size and sterilization method generally determine the best wrapping material, most commonly paper, plastic, nylon, cloth, or combinations of these materials. Seal packages by heat, tape, and self-sealing methods. Wrap instruments loosely to allow the sterilizing agent to circulate freely throughout the pack. Pack scissors, hemostats, and hinged instruments in the open position so the sterilizing agent can reach all parts. When wrapping in an easily punctured material, cover the tips of sharp instruments with 2 x 2 gauze or cotton roll. If using plastic or nylon sterilization tubing, the pack should be approximately 20% larger than the longest instrument to allow the inside air to expand when heated. Clear tubing is relatively puncture-resistant and enables rapid identification of contents. When using cloth to wrap critical items, use a double thickness. Date all packs.

c. Heat Sterilization.

- (1) The best way to minimize cross-contamination is to sterilize all instruments that can withstand sterilizing conditions. The most practical, dependable sterilization method, heat, when appropriate, is preferable to chemical means. These are the most common heat sterilization techniques:
 - (a) Steam Vapor Under Pressure Sterilizer (Autoclave). Steam vapor under pressure is an excellent sterilization method. Moist heat kills the bacteria by causing their proteins to denature and coagulate within the microbial cell. The steam's high temperature, not the pressure, kills the microorganisms. Steam can rust cutting edges made of carbon steel; however, antirust agents reduce this process.
 - (b) Chemical Vapor Under Pressure Sterilizer (Chemiclave). This sterilizer uses chemical vapor under pressure and kills bacteria in much the same manner as the steam sterilizer. It is an excellent sterilization method. Because chemical vapors are less corrosive than steam, they do not dull sharpened instruments. Chemical vapor sterilizers use a specific mixture of formaldehyde, alcohols, ketone, acetone, and water. If the manufacturer's recommended chemical solution is not available, distilled water may be used for a short time Use chemical solutions only once. A disadvantage of the chemical vapor sterilizer is the residual chemical vapor that escapes into the air when the chamber door is opened. While

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- non-toxic and non-mutagenic, its odor can be objectionable. Allowing the sterilizer to cool for at least 20 minutes before opening will significantly reduce the residual vapor level. A commercial purging system that reduces residual vapor levels is available.
- (c) <u>Dry Heat Sterilizer</u>. Dry heat kills bacteria by an oxidation process. Dry heat sterilization will not corrode instruments, but dry heat sterilizers can destroy metal instruments' temper and melt solder joints if not monitored properly. Some dry heat units are not able to sterilize large trays and require special wrapping and bagging materials. For these reasons, dry heat sterilization is not recommended for critical instruments, and should be monitored carefully and used judiciously with semi-critical and non-critical instruments. Because sterility is destroyed as soon as items are touched or left open to the environment, do not place loose instruments in dry heat sterilizers. Wrap and bag all instruments; they must remain wrapped or bagged until used.

d. Sterilization Monitoring.

- (1) <u>Chemical Indicators</u>. External and internal chemical indictors provide a quick visual check to verify instruments have been exposed to elevated temperatures. They do not guarantee the instruments are sterile. External chemical indicators (autoclave tape or sterilizing bags with heat-sensitive printing) identify at a glance which instruments have been processed but show only the outside of the pack was exposed to an elevated temperature. An external chemical indicator must be on every pack processed. If using see-through packages, a chemical indicator placed inside the pouch is acceptable. Internal chemical indicators, available in strips, cards, or labels, react to time/temperature/ sterilizing agent combinations.
- (2) <u>Biological Spore Monitors (BSM)</u>. Bacterial spores resist heat destruction better than do vegetative forms of bacteria and viruses. Therefore, the spores are used to verify a sterilizer's effectiveness. Place them in the most challenging area of the load being tested and wrap the pack in the usual fashion. Monitor all chemical vapor, water vapor, and dry heat sterilizers with a spore test either weekly or each cycle, whichever is less frequent.
 - (a) These systems require a either medical laboratory service or an in-house incubator to incubate the test spore. Dry heat sterilizers require an alternate system using a glassine envelope with enclosed spore strips. Regardless of the system used, document spore monitoring, including identification test date, test results, and operator, and maintain the records for two years.
 - (b) If a spore monitor tests positive (spores are still alive), check the sterilizer for proper use and function and repeat the spore test. Items need not be recalled because of a single positive spore test. However, do not routinely use the unit in question until after obtaining a second test.

If the second test also is positive, the unit requires service or repair. When the unit is returned to use, perform a spore test to ensure the unit is in proper operating condition.

(3) <u>Storage and Shelf Life</u>. Store sterile instruments and packs in a cabinet or drawer to reduce contact with aerosols and dust. Handle them as little as possible before using them. Instrument pack life varies according to wrapping material as follows:

| Metal or Plastic Container | 30 days |
|--|-----------|
| Paper Wrap | 30 days |
| Cloth (Double Thickness) | 2 months |
| Nylon, Plastic, or Plastic-Paper Combination (Tape Sealed) | 6 months |
| Nylon, Plastic, or Plastic-Paper Combination (Heat Sealed) | 12 months |

Rewrap and resterilize outdated packs or packs suspected of being contaminated. Rotate packs to use the oldest ones first. Keep loose (unwrapped or unpacked) instruments to an absolute minimum as their sterility cannot be ensured. Recycle loose reusable instruments through a sterilizer at least once every two weeks. Disinfect drawers and instrument holders containing loose instruments monthly.

e. Chemical Sterilization and High-Level Disinfection. Although heat is the preferred sterilization method, certain instruments and plastics will not tolerate heat sterilization and require chemical sterilization or high-level disinfection. These disinfectants destroy microorganisms by damaging their proteins and nucleic acids. Most formulae contain 2% glutaraldehyde and come in two containers. Mixing the proper amounts from each container activates the solution. Sterilization monitors cannot verify glutaraldehyde sterilization. The solution is caustic to the skin, so use forceps or rubber gloves to handle instruments immersed in glutaraldehyde and *always* follow manufacturer's directions *carefully*. Label each container of fresh solution with an expiration date. Uninterrupted immersion for 7 to 10 hours in a fresh glutaraldehyde solution usually will achieve sterilization; uninterrupted immersion for 10 minutes will kill most pathogenic organisms, but not spores. Heavily soiled or contaminated instruments render glutaraldehydes ineffective. Debride instruments thoroughly to disinfect effectively. Glutaraldehydes are not recommended for surface disinfection.

f. Surface Disinfection.

(1) Extraordinary efforts to disinfect or sterilize environmental surfaces such as walls, floors, and ceilings generally are not required because these surfaces generally do not transmit infections to patients or health care workers. However, routinely clean and remove soil from them.

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- (2) After contamination, wipe all other treatment room surfaces such as countertops, dental chairs, light units, exam tables, and non-sterile objects in the operating field with absorbent toweling to remove any extraneous organic material, and then disinfect them with a suitable chemical germicide. Personnel shall wear heavy-duty ("Nitrile") rubber utility gloves when applying surface disinfectants. Many different chemical disinfectants possessing varying degrees of effectiveness are available. The following three surface disinfectants are recommended.
 - (a) <u>Iodophor</u>. Iodophor compounds contain 0.05 to 1.6% iodine and surface-active agents, usually detergents, which carry and release free iodine. Iodophor's antimicrobial activity is greater than that of iodine alone: 10 to 30 minutes of contact produces intermediate levels of disinfection. Iodophors are EPA-approved as effective when diluted 1:213 with water. Because iodine's vapor pressure is reduced in iodophor, its odor is not as offensive. In addition, iodophors do not stain as readily as iodine.
 - (b) <u>Phenolics</u>. In high concentrations, phenolic compounds are protoplasmic poisons. In low concentrations, they deactivate essential enzyme systems. As disinfectants, phenolics are usually combined with a detergent; 10 to 20 minutes of contact produces disinfection. Phenolics are less corrosive to treated surfaces.
 - (c) Sodium Hypochlorite. Sodium hypochlorite is thought to oxidize microbial enzymes and cell wall components. A 1:10 dilution of 5.25% sodium hypochlorite in water produces a solution which disinfects at an intermediate level in 10 minutes. Sodium hypochlorite solution tends to be unstable, so prepare a fresh solution daily. It possesses a strong odor and can harm eyes, skin, clothing, upholstery, and metals (especially aluminum
- (3) Chemical Disinfectants Not Recommended For Use.
 - (a) Alcohol. Alcohol is bacteriocidal against bacterial vegetative forms by denaturing cellular proteins. Diluted in water, a 70 to 90% solution is more effective than a more concentrated solution. Alcohol's disadvantages are: (1) rapid evaporation, (2) lack of sporicidal or viricidal activity, and (3) rapid inactivation by organic material. Since alcohol interferes with proper surface cleansing, it has no place in the disinfection protocol.
 - (b) Quaternary Ammonium Compounds. In the past, benzalkonium chlorides and other "quats" were used as disinfectants because they were thought to be safe and inexpensive and have low surface tension. Their biocidal activity breaks down the bacterial cell membrane, producing an altered cellular permeability. As a group, these compounds have serious

deficiencies. Being positively charged, they are attracted to not only bacteria but also to glass, cotton, and proteins, which decrease their biocidal activity. Common cleaners', soaps', and other compounds' negatively charged ions neutralize "quats." Research has shown some "quats" support the growth of gram-negative organisms. Quats are ineffective against most spore formers, the Hepatitis B virus, and the tubercle bacillus.

- 10. <u>Laundry</u>. Although research has identified soiled linens as a source of large numbers of certain pathogenic microorganisms, the risk of linens actually transmitting disease is negligible. Rather than rigid procedures and specifications, hygienic and common-sense storage and processing of clean and soiled linen are recommended. Wearing gloves while handling soiled linen is recommended. Handle it as little as possible and with minimum agitation to prevent gross microbial contamination of the air and persons handling the linen. Carefully check linen for sharps objects and remove them before washing. Bag all soiled linen where used; do not sort or rinse it in patient care areas. Place and transport linen soiled with blood or body fluids in bags that prevent leakage. Use normal laundry cycles according to the washer and detergent manufacturers' recommendations.
- 11. Cleaning and Decontaminating Blood or Other Body Fluid Spills. Use an EPA-approved germicide or recommended surface disinfectant agent to promptly clean all blood and blood-contaminated fluid spills. Health care workers must wear gloves. First remove visible material with disposable towels or other appropriate means that prevent direct contact with blood. If anticipating splashing, wear protective eyewear and an impervious gown or apron that provides an effective barrier to splashes. Next decontaminate the area with disinfectant solution or an appropriate EPA-approved germicide. Clean and decontaminate soiled cleaning equipment or put it in an appropriate container and dispose of it according to clinic policy. Use plastic bags clearly labeled as containing infectious waste to remove contaminated items from the spill site. Remove gloves; then wash hands.

12. Infectious Waste.

a. Epidemiological evidence does not suggest most clinic waste is any more infectious than residential waste. However, public concern about the risk of medical wastes must not be ignored. Identifying wastes for which special precautions are necessary include those wastes which potentially cause infection during handling and disposal and for which special precautions appear prudent, including sharps, microbiology laboratory waste, pathology waste, and blood specimens or products. While any item that has touched blood, exudates, or secretions potentially may be infectious, it is usually not considered practical or necessary to treat all such waste as infectious. Materials containing small amounts of blood, saliva, or other secretions such as tainted gauze pads, sanitary napkins, or facial tissues are not considered infectious waste. Generally, autoclave or incinerate infectious waste before disposing of it in a sanitary landfill. Infectious waste autoclaving standards are different from normal sterilization standards. Carefully pour bulk blood, suctioned fluids, excretions, and

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- secretions down a drain connected to a sanitary sewer. Or for materials capable of it, grind and flush such items into sanitary sewers (some states prohibit this practice).
- b. The Environmental Protection Agency classifies health care facilities as generators of infectious waste based on the weight of waste generated. Coast Guard classification is based on facility type. All Coast Guard clinics are considered generators. Each Coast Guard health care facility must have a written infectious waste management protocol consistent with state and local regulations in the unit's area.
- c. <u>Biohazard warning labels shall be affixed to regulated waste containers; refrigerators, and freezers containing blood or other potentially infectious material;</u> and other containers used to store, transport, or ship blood or other potentially infectious materials with these exceptions:
 - (1) Substitute red bags for labels on regulated waste bags or containers. OSHA believes red bags protect personnel because they must comply with OSHA BBP Standard Paragraph (g)(2)(iv)(M), which requires training personnel to understand the meaning of all color coding.
 - (2) Individual containers of blood or other potentially infectious materials placed in a labeled container during storage, transport, shipment or disposal.

13. Managing Exposures (Needle Stick Protocol)

a. Exposure.

- (1) An exposure occurs if a health care worker comes in contact with blood or other body fluids in one of these ways:
 - (a) Parenteral—through a needle stick or cut;
 - (b) Mucous membrane—from a splash to the eye or mouth;
 - (c) Cutaneous—contact with large amounts of blood or prolonged contact with blood when the health care worker's exposed skin is chapped, abraded, or afflicted with dermatitis.
- (2) All individuals so exposed shall report the exposure to their immediate supervisor, who will document the incident in a memorandum detailing the exposure's time, date, and circumstances and any medical treatment received to the Chief, Health Services Division or health services department head, with a copy to the exposed person. The QA coordinator or his or her designee also will retain a copy and ensure all required follow-up treatment and testing is documented. The Chief, Health Services Division or health services department head shall ensure that the following this management protocol is adhered
- (3) After an exposure, obtain the source person's consent, making sure to follow local laws governing consent for testing non-active duty source persons and incompetent or unconscious persons. At a location where appropriate pre-test counseling is available for the source person, draw a blood sample and test it

for Hepatitis B Surface Antigen (HbsAg) and Human Immunodeficiency Virus (HIV) antibody. Provide the source person post-test counseling and treatment referrals. Inform the exposed person of the source person's test results and applicable laws and regulations on disclosing the source person's identity and infectious status. It is extremely important all persons who seek consultation for any HIV-related concerns receive appropriate counseling from a USMTF or other medical facility capable of providing this service.

- (4) All clinics shall ensure the health care professional evaluating an employee after an exposure incident has this information:
 - (a) A copy of the OSHA BBP Standard,
 - (b) A description of the exposed employee's duties as they relate to the exposure incident,
 - (c) Documentation of the route(s) of exposure and circumstances under which exposure occurred,
 - (d) Results of the source individual's blood tests, if available; and all records on the employee's appropriate treatment, including vaccination.
- (5) The SMO shall obtain and give the exposed person a copy of the evaluating health care professional's written opinion within 15 days after the evaluation is complete.
- (6) Figure 13-K-1 presents a sample needle stick injury flow sheet.
- b. Hepatitis B Virus Post-exposure Management.
 - (1) For a worker exposed to a source individual found to be positive for HbsAg:
 - (a) The exposed worker who has not previously received Hepatitis B vaccine will receive the vaccine series. A single dose of Hepatitis B immune globulin (HBIG) if it can be given within 7 days of exposure is also recommended.
 - (b) Test the exposed worker who has previously received Hepatitis B vaccine for antibody to Hepatitis B surface antigen (anti-HBs). If the antibody level in the worker's blood sample is inadequate (i.e., less than 10 SRU by RIA, negative by EIA) give the exposed employee one dose of vaccine and one dose of HBIG.
 - (2) If the source individual is negative for HbsAg and the worker has not been vaccinated, the worker shall receive Hepatitis B vaccination.
 - (3) If the source individual refuses testing or cannot be identified, the unvaccinated worker should receive the Hepatitis B vaccine series. Consider administering HBIG on an individual basis if the source individual is known or suspected to be at high risk of HBV infection. At his or her discretion the responsible

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medical officer will manage and treat as needed previously vaccinated workers who are exposed to a source who refuses testing or is not identifiable.

c. Human Immunodeficiency Virus Post-exposure Management.

- (1) If a worker is exposed to a source individual found positive for HIV infection or who refuses testing, counsel the exposed worker about the risk of infection and evaluate him or her clinically and serologically for evidence of HIV infection as soon as possible after the exposure. In view of the evolving nature of HIV post-exposure management, the health care provider must be well informed of current Centers for Disease Control (CDC) guidelines on this subject.
 - (a) Advise the exposed worker to report and seek medical evaluation for any acute febrile illness occurring within 12 weeks after exposure. Such an illness, particularly one characterized by fever, rash, or lymphadenopathy, may indicate recent HIV infection.
 - (b) After the initial test at the time of exposure, retest seronegative workers 6 weeks, 12 weeks, and 6 months after exposure to determine whether HIV transmission has occurred. During this follow-up period (especially the first 6 to 12 weeks after exposure, when most infected persons seroconvert), exposed workers must follow CDC recommendations to prevent transmitting HIV, including refraining from blood donation, informing health care workers rendering treatment of his or her status, and using appropriate protection during sexual intercourse. During all phases of follow-up, it is vital to protect worker confidentiality.
- (2) If the source individual's tests are seronegative, perform a baseline testing of the exposed worker with optional follow-up testing 12 weeks later if the worker desires or the health care provider recommends it. After the initial test at the time of exposure, at the responsible medical officer's discretion, retest consenting seronegative source individuals at 12 weeks and 6 months afterward.
- (3) If the source individual cannot be identified, decide appropriate follow-up on an individual basis. All workers concerned they have been infected with HIV through an occupational exposure should undergo serologic testing
- (4) Follow CDC recommendations for preventing HIV and HBV transmission to patients during exposure-prone procedures, defined as those invasive procedures with a recognized risk of percutaneous injury to health care workers.
 - (a) All health care workers shall adhere to universal precautions. Health care workers with exuding lesions or weeping dermatitis shall refrain from all direct patient care. Health care workers shall comply with current CDC guidelines for disinfecting and sterilizing equipment and supplies.

- (b) All health care workers performing exposure-prone procedures shall know their HIV and HBV status.
- (c) All health care workers who are HIV or HBV positive shall refrain from performing exposure-prone procedures.
- 14. <u>Training Personnel For Occupational Exposure</u>. All Health Services Divisions or Branches will inform and train personnel in occupational exposure initially on assignment and annually thereafter. Personnel who have taken appropriate training within the past year need receive additional training only on subjects not previously covered. The training program shall contain at least these elements:
 - a. An accessible copy and explanation of the regulatory text of this standard (Federal Register 56 (235):64175, December 6, 1991 [29 USC 1910.1030]).
 - b. A general explanation of the epidemiology and symptoms of bloodborne diseases.
 - c. An explanation of bloodborne pathogen transmission modes.
 - d. An explanation of the exposure control plan outlined in Section 13-K.
 - e. <u>An explanation of the appropriate methods to recognize tasks and other activities that</u> may involve exposure to blood and other potentially infectious materials.
 - f. An explanation of methods to reduce or prevent exposure, such as barrier techniques, and their limitations.
 - g. <u>Information on the types and properly using, locating, removing, handling,</u> decontaminating, and disposing of personal protective equipment.
 - h. An explanation of the basis for selecting personal protective equipment.
 - i. <u>Information on the Hepatitis B vaccine, including efficacy, safety, administration, and benefits</u>. This vaccination is mandatory for all Health Services Technicians except E-8 and E-9 personnel in administrative positions. It is recommended and available for EMTs and E-8 and E-9 Health Services Technicians in administrative positions.
 - j. <u>Information on appropriate actions to take and persons to contact in an emergency</u> involving blood or other potentially infectious materials.
 - k. An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and available medical follow-up described in Section 13-K-13.
 - 1. <u>Information on the post-exposure evaluation and follow-up the SMO or designee</u> is required to provide for the employee after an exposure incident.

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m. An explanation of the signs, labels, and/or color coding required for sharps and biohazardous materials.

n. A question-and-answer period with the person conducting the training session.

Figure 13-K-1

SAMPLE NEEDLESTICK INJURY FLOWSHEET (CONFIDENTIAL)

| Health Care Worker's Name: Source's name, status, and contact information (if known): | | | | | | | |
|---|---|--|-------------|---------------|--|--|--|
| | | | | | | | |
| | | | | | | | |
| | | cident: | | | | | |
| | | xposure (check one) | | | | | |
| | ☐ Needle stick, cut, or puncture wound with contaminated instrument | | | | | | |
| | | Splash to the eye or mouth | | | | | |
| | | Contact with large amounts of blood when the exposed skin is chapped, abraded, or afflicted with dermatitis | | | | | |
| | | Other: | | | | | |
| | | | <u>No</u> | <u>Yes</u> | | | |
| Have consent to test and pretest information been given? | | | | | | | |
| Is source test positive for HBV? | | | (2) | \Box (next) | | | |
| Is Health Care Worker (HCW) vaccinated for hepatitis? | | | (2) | \Box (next) | | | |
| HCW Hepatitis B surface antigen (anti-HBs) adequate (i.e., more than 10 SRU by RIA, positive by EIA)? | | | (3) | ☐ (next) | | | |
| Less than 7 days since exposure? | | | (7) | (4) | | | |
| Is source test positive for HIV? | | | (5) | \Box (1, 6) | | | |
| AC | TION | TAKEN | | | | | |
| 2. 3. 4. 5. 6. 7. | Initiate Give of HIV to HIV T No acc | e and complete HBV vaccination series one dose of HBV vaccine one dose of HBIG esting (baseline, optional 12 weeks) Festing (baseline, 6 weeks, 12 weeks, 6 months) tion required | | | | | |
| SENT TO QA COMMITTEE: | | | | | | | |

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Section L - Risk Management Program

- 1. <u>Purpose</u>. The risk management program supports quality medical care by identifying, analyzing, and preventing actual and potential risks to patients and staff. The program provides mechanisms to detect and prevent accidents and injuries and reduces the cost of claims and loss of other resources.
- 2. <u>Background</u>. Risk management programs are most effective if they are prospective, preventive, and comprehensive. All staff members, beneficiaries, contract providers, and volunteers shall be aware of risks in the clinical environment and act safely and responsibly to implement program requirements. Risk management activities are not limited to claims activities but examine all instances of actual and potential risk or loss.

3. Definitions.

- a. <u>Medical Incident</u>: An adverse or unexpected medical outcome resulting in death or significant morbidity.
- b. Occurrence: Any event or situation in which there is an actual or potential injury or patients or staff raise a significant complaint or concern about treatment delivered.

4. Informed Consent.

c. <u>Background</u>. Every person, with a few exceptions, has the right to be examined and treated only in the manner they authorize. This individual prerogative is based on the concept a competent patient has the right to make informed decisions about health care. Consent for health care must be informed, voluntary, competent, and specific, and is clearly an important issue in quality patient care. The objective of informed consent is improved patient-provider communication in non-emergent situations, which should result in patients' realistic expectations about the nature of treatment and the expected outcome, and reduced liability for the government. Clear documentation demonstrating the patient was properly informed is necessary to protect the patient, the provider, and the government. Although patients must be informed of treatment options, military members who refuse treatment necessary to render them fit for duty (including immunization) are subject to separation and/or disciplinary action (see Chapter 2-A-4-b.).

d. Responsibilities.

- (1) <u>Chief, Health Services Division (CHSD)</u>: The CHSD must publish facility-specific implementing instructions that ensure providers carry out the spirit and intent of this Section. The CHSD and cognizant MLC should monitor compliance with consent policies and procedures as a regular part of medical and dental records review.
- (2) <u>Health Care Providers</u>: Responsible health care providers must counsel patients before treatment and document receiving the patient's informed consent.

- e. <u>Types of Consent</u>. Consent may be expressed or implied.
 - (1) <u>Expressed Consent</u>: This type of consent is obtained by open discussion between the provider and patient and must include a statement the patient consents to the proposed procedure. Expressed consent may be oral or written.
 - (a) Oral Consent. Except where this regulation specifically requires written consent, oral consent is sufficient authorization for treatment. However, oral consent is difficult to prove. If a health care provider receives oral consent to treatment, he or she must document it by an entry in the treatment record. Consent received from competent authority by telephone is a form of oral expressed consent; a person not directly involved in the patient's care should witness such consent; and it must be document it by an entry in the treatment record.
 - (b) Conditions Requiring Written Consent. Document written consent by having the patient sign forms authorizing treatment and including an entry in the treatment record that discusses the requirements outlined in Paragraph 13-L-4. Except in emergencies, written consent is required for these situations:
 - All surgical procedures (including, among others, placing sutures, incision and drainage, removing a foreign body(s), cauterizing, removing wart(s), injecting medications into a joint(s), etc.)
 - 2 Invasive tests and procedures to diagnose and treat disease or remove tissue specimens (e.g., biopsies), except routine phlebotomy.
 - 3 Anesthesia, except local dental anesthesia.
 - <u>4</u> Dental procedures other than routine restorative dentistry.
 - <u>5</u> Genitourinary procedures including vasectomies, IUD insertion or removal, etc.
 - (2) <u>Implied Consent</u>. Implied consent is derived from the patient's conduct even if he or she does not communicate specific words of consent. Assume implied consent only if one can reasonably presume the patient knows the risks, benefits, and alternatives to treatment. For example, a patient's presence at dental sick call is implied consent for a dental exam. Never accept implied consent to treatment involving surgical therapy or invasive diagnostic procedures except in emergencies.
- f. <u>Emergencies</u>. Consent before treatment is not necessary when immediate treatment is required to preserve life or prevent deterioration of the patient's condition. The provider will document the existence and scope of the emergency and describe the events precluding obtaining consent.

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- g. Who May Consent. Generally, competent adult patients who have the capacity to manage their own affairs who present themselves for treatment have the authority to consent. If a patient is incompetent due either to statutory incompetence (e.g., a minor) or mental impairment, then it must determined who the individual with legal capacity to consent and obtain his or her consent before examining or treating the patient. Laws defining minors and to what they may legally consent differ by state. The law of the state where the facility is located governs legal capacity to consent. Each clinic will develop a policy for treating minors.
- h. <u>Information To Provide</u>. The provider must advise the patient of the nature of his or her condition; describe the proposed treatment in terms the patient can understand; and explain the material risks and expected benefits of the proposed treatment course, available alternative health care options, and the option of non-treatment. A material risk is one a reasonable person likely would consider significant in deciding whether to undertake therapy and is a function of the likelihood of occurrence, the severity of the injury it threatens to cause, and existing reasonable alternatives. A provider is not required to explain risk that are considered extremely remote unless the patient requests an explanation or the potential adverse consequences are so grave a reasonable person in the patient's particular circumstances would consider the risk important.
- i. <u>Informing the Patient</u>. Health care providers will provide information in a manner that allows a patient of ordinary understanding to intelligently weigh the risks and benefits when faced with the choice of selecting among the alternatives or refusing treatment altogether. Health care providers must communicate in language one can reasonably expect the patient to understand. Although open discussions between the responsible health care provider and the patient should be the standard, each department may develop internal methods to acquaint patients with the benefits, risks, and alternatives to procedures requiring consent. In some departments, prepared pamphlets or information sheets may be desirable.
- j. <u>Documentation</u>. Regardless of the method used to inform the patient or the form of consent (oral or written), the provider must document the disclosure and the patient's reactions in the medical or dental record. It is highly recommended progress notes even if the patient has signed a preprinted "consent" form. Progress notes written to document disclosing information to the patient will be specific about the information provided. The notes must specifically enumerate risks, alternative forms of treatment, and expected benefits the provider discussed with the patient. Use SF 522, "Request for Administration of Anesthesia and for Performance of Operations and Other Procedures," to document consent in all surgical, anesthetic and reproductive procedures other than local dental anesthesia and routine restorative dentistry.
- k. <u>Witness to Consent</u>. All consent forms require a witness's signature. The witness may be a health care facility member who is not participating in the procedure or treatment. Patients' relatives are not acceptable as witnesses. The witness confirms the patient signed the form, not that he or she received all relevant information.

- 1. <u>Duration of Consent</u>. Consent is valid as long as no material change in circumstances occurs between the date the patient consented and the procedure or treatment date. Obtain new consent if a material change in circumstances occurs, for example the provisional diagnosis changes. If more than seven (7) days elapse between the date the patient signed the consent and the date treatment begins, provider and patient must re-sign, re-initial, and re-date the consent form. A new consent is not required for each stage in a series of treatments for a specific medical condition, e.g., repeated application of liquid nitrogen to warts.
- 5. Occurrence Monitoring and Reporting. (To be developed).
- 6. <u>Medical Incident Monitoring and Reporting</u>.
 - a. <u>Definition</u>. In the Coast Guard's Health Services Program, a medical incident is an event involving an unexpected death or permanent disability of a patient to whom Coast Guard health services personnel have rendered health care. The event is not reviewed to place blame or discipline those involved, but rather to assess the health care process(es) involved and identify potential areas for improvement. The Coast Guard uses the resulting recommendations to determine health care policy, personnel, equipment, and training needs to prevent future adverse health care outcomes. A single event may result in initiating a Mishap Board as the Safety and Environmental Health Manual, COMDTINST M5100.47 (series), requires and a legal investigation conducted concurrently with a medical incident review of the same event (e.g., a vessel collision with injuries). In most cases however, a medical incident review will occur solely within a Coast Guard health care facility or with medical or dental services rendered its only issue.
 - b. Reporting Procedure. Within 24 hours after a medical incident occurs, the command shall submit copy(s) of SF-558, Emergency Care and Treatment Report, and/or SF-600 for events occurring within the clinic and/or CG-5214, Emergency Medical Treatment Report, for events occurring outside the clinic to the appropriate MLC (k). Clearly mark "Incident Report" in large print across the top of these forms. Stamp or print this statement on the top of each document: "This is a medical quality assurance document. It is protected by Federal law (14 USC 645)." MLC (k) shall send copies of the documents to Commandant (G-WKH) within three days of receipt.
 - c. Review Procedure. On receiving one of the three forms, MLC (k) or Commandant (G-WKH), if appropriate, shall review the document(s); verify the event meets the Paragraph 13-L-6-a criteria for an incident; determine whether an on-site medical review shall be conducted; and designate a single point of contact at MLC (k) or Commandant (G-WKH).
 - (1) If MLC (k), or Commandant (G-WKH), determines a medical incident review is unnecessary, they shall notify the command by letter within 10 working days of the event and send a copy of the letter to Commandant (G-WKH).
 - (2) If conducting an on-site medical incident review, MLC (k) or Commandant (G-WKH), as appropriate, shall notify the involved command as soon as possible and designate an officer to conduct a review or convene a panel of

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qualified professional staff, including a member of the involved facility, to review all aspects of the incident. To ensure confidentiality, the panel shall consist of only the designated facility point of contact and the persons MLC (k) or Commandant (G-WKH) appoint.

- d. The incident review officer or panel shall request and review all relevant documents and reports, interview personnel as required, and when the review is complete, submit a written letter report with this information on the incident to Commandant (G-WKH) through the cognizant MLC (k) (see Paragraph 13-L-6-e below):
 - (1) <u>Synopsis</u>. A brief summary of the incident and injuries and/or fatalities involved.
 - (2) <u>Factual Information</u>. Factual information and data about the incident and personnel involved shall consist of at least these topics:
 - (a) History. The chronological order of any significant events preceding, during, and after the incident, including any written logs or transcripts of radio logs substantiating this chronology, such as the SF-558, CG-5214, or SF-600.
 - (b) Injuries. Describe each injury, or in the case of fatalities, the cause of death. Include autopsy findings when available.
 - (c) Professional qualifications of all persons who delivered health care, including all recent applicable training and certificates (e.g., ACLS, BLS, EMT, HS, etc.).
 - (d) Equipment Performance. List all pertinent medical equipment used during the incident and any failures due to mechanical malfunction, operator error, inadequate training, or other factors. Describe whether equipment involved was maintained or serviced according to manufacturers' specifications.
 - (3) Analysis and Conclusions. The individual's or panel's hypothesis of the circumstances surrounding the event, emphasizing the health care aspect, developed using all available information and including a brief conclusion about the health care rendered and how it contributed to the event's outcome.
 - (4) Recommendations. Recommended modifications to policy, personnel staffing, equipment, training, or any other health care delivery system aspect which might improve to avoid similar incidents in the future.
- e. <u>Routing Incident Review Reports</u>. The cognizant MLC (k) shall send the completed report to Commandant (G-WKH) for review and appropriate action.

Section M - <u>Training and Education</u>

1. Definitions.

- a. <u>ACLS (Advanced Cardiac Life Support)</u>: Sponsored by the American Heart Association (AHA), this 16-hour program (8 hours for recertification) emphasizes cardiac-related diagnostic and therapeutic techniques and grants a completion certificate valid for two years on completion. An ACLS certificate of completion recognizes a person completed the course and does not in any way authorize him or her to perform skills taught there. ACLS also sometimes refers to the cardiac component of Advanced Life Support.
- b. <u>Advanced Life Support (ALS)</u>: A general term applied to pre-hospital skills beyond the basic life support level including, among others, EKG interpretation, medication administration, and advanced airway techniques.
- c. <u>Basic Life Support (BLS)</u>: Rudimentary pre-hospital skills including CPR, bleeding control, splinting, patient assessment, oxygen administration, etc., associated with the basic level emergency medical technician.
- d. <u>Cardio-Pulmonary Resuscitation(CPR)</u>: A program sponsored by the AHA and American Red Cross which, on completion, grants certificates of completion for 1 to 2 years. The course curriculum includes basic skills (airway maintenance and cardiac compression) necessary to sustain heart and brain function until advanced skills can be administered.
- e. <u>Emergency Medical Technician (EMT)</u>: A general term referring to the certification of pre-hospital care providers routinely recognizes at three skill levels (EMT-Basic, EMT-Intermediate, EMT-Paramedic), but functions performed at each level vary significantly by jurisdiction. When the term EMT is used alone, assumes it refers to the EMT-Basic level, which performs BLS skills.
- f. <u>Paramedic</u>: An individual certified by the National Registry of Emergency Medical Technicians as an Emergency Medical Technician-Paramedic (NREMTP) or certified by a local governing body to perform ALS procedures under a physician's license.

2. Unit Health Services Training Plan (In-Service Training).

a. <u>Clinics, sickbays, and independent duty health services technicians</u> must have an ongoing in-service training program aimed at all providers with emphasis on the Health Services Technicians' professional development. It is expected of clinic staff members attending outside training to share new information with other staff members. In-service training sessions allow clinics to ensure issues of clinical significance are presented to their staff.

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- b. <u>In-service training must include these topics, among others:</u>
 - (1) Quality Assurance Implementation Guide Exercises;
 - (2) Annual review of clinic protocols on suicide, sexual assault, and family violence;
 - (3) Patient satisfaction issues;
 - (4) Patient sensitivity;
 - (5) Emergency I.V. therapy;
 - (6) Pneumatic anti-shock garment (MAST) review;
 - (7) Emergency airway management;
 - (8) Cardiac monitor and defibrillator familiarization;
 - (9) Cervical spine immobilization and patient transport equipment;
 - (10) Emergency vehicle operator's training (where operated);
 - (11) Section 13-K infection control policy and procedures.
- c. <u>The Chief, Health Services Division, must designate in writing a Health Services Training Coordinator (HSTC)</u> who coordinates clinic in-service training, distributes a quarterly training schedule, and maintains the unit's health services training record. The HSTC's responsibilities include these:
 - (1) Establishes and maintains a Health Services Training Record to document all training conducted within the clinic. Records should include presentation outline, title, program date, name of presenter, and list of attendees. Maintain training records for 3 years from the date on which training occurred.
 - (2) Ensures all emergency medical training is documented in the individual's Coast Guard Training Record (CG-5285) for credit toward the 48-hour National Registry EMT continuing education requirement.
 - (3) Maintains a Training Record section that records personnel certifications including CPR, ACLS, EMT, and flight qualifications, including expiration dates and copies of the current certificate. The HSTC should ensure assigned personnel obtain recertification before current certificates expire.
- 3. Emergency Medical Training Requirements.
 - a. All active duty, civilian, and contract civilian personnel working in Coast Guard clinics and sick bays shall maintain current CPR certification at the health care provider level (AHA "C" Course or equivalent).
 - b. Every Health Services Technician who participates in SAR or MEDEVAC operations must be a currently certified EMT. At least one currently certified EMT will staff Coast Guard emergency vehicles. Unit commanding officers shall ensure HSs are trained in sufficient numbers under Section 13-M-3.h to meet this requirement.

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- c. At least one medical officer per clinic will maintain current ACLS certification.
- d. Only licensed or certified physicians, nurse practitioners, physician assistants, or Nationally Registered advanced life support providers (EMT-P and EMT-I) will perform ALS procedures, except as Section 13-M-3.e stipulates. Paramedics may perform functions authorized by their certifying jurisdiction's protocols with written medical officer authority.
- e. Other than those permitted in the Standardized Health Services Technician
 Formulary, (COMDTINST 6570.1), an HS in SAR or MEDEVAC situations may
 provide ALS procedures and medications only if his or her supervising medical
 officer authorizes such provision in writing and assumes responsibility for those
 procedures and medications. In emergencies, the supervising medical officer may so
 authorize by radio.
- f. Other than those described in Sections 13-M-3.d and 13-M-3.e, persons who have completed an ACLS course should note certification means only they have completed the course and does not convey a license to perform any skill. Individuals completing ACLS courses shall serve as a clinic resource on current standards for pre-hospital care in training and equipment areas.
- g. <u>Emergency vehicles shall be equipped to provide basic life support (BLS) only.</u> The clinic shall maintain equipment (monitor-defibrillator, advanced airway kit etc.) and medications to provide ALS services at in a reserve status and add them when necessary if authorized ALS providers are available.
- h. To obtain required EMT training (basic course or recertification), commands shall use local military sources if available. Usually most public service training agencies or community colleges offering training can accept Coast Guard personnel. If the required training is not available from a civilian or military source within a 50-mile radius, commands may use other cost-effective training sources. Submit requests through the chain of command to Commandant (G-WKH) with these items:
 - (1) CG-5223, Short-Term Resident Training Request;
 - (2) SF-182, Request, Authorization, Agreement and Certification of Training;
 - (3) Requests for training outside a 50-mile radius which incur per diem expense require the unit commanding officer's or officer-in-charge's statement local training sources are unavailable.

4. Health Services Technician "A" School.

a. The Office of Personnel and Training operates the 20-week introductory course for Health Services Technicians, including the Emergency Medical Technician (EMT) course, at TRACEN Petaluma. As program manager, Commandant (G-WKH) provides professional comments to the TRACEN on curriculum and qualifying requirements. Commandant (G-PRF) controls HS "A" School personnel quotas. The Training and Education Manual, COMDTINST M1500.1 (series), outlines selection requirements and procedures.

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5. Health Services Technician "C" Schools.

- a. <u>Due to the specialized nature of health care</u>, the Coast Guard requires health services technicians to complete training in medical specialty fields such as aviation medicine, preventive medicine, medical and dental equipment repair, physical therapy, eye specialist, laboratory, radiology, pharmacy, and independent-duty specialties. The usual sources are Department of Defense training programs.
- b. <u>Selection for HS "C" Schools is based on qualification code requirements for HS billets at clinics and independent duty sites</u> as specified in personnel allowance lists. Secondary selection criteria include command requests, personnel requests, and deficiencies noted on MLC Quality Assurance Site Surveys.
- c. <u>HS personnel should submit a CG-5223, Short-Term Resident Training Request,</u> with Command endorsement to Commandant (G-WKH) through the appropriate chain of command. Commandant (G-WKH) must receive this request at least 45 days before the training convening date.
- d. <u>HS personnel wishing to pursue "C" school training in courses of 20 weeks or longer require a permanent change of duty station coordinated by Military Personnel Command (CGPC).</u> Submit requests on CG-3698A, Assignment Data Form, to Military Personnel Command (CGPC-emp).

6. Continuing Education Programs.

- a. <u>All U.S. Public Health Service Officers and Coast Guard physician assistants</u> must maintain active professional licenses and/or certification to practice their professional specialty while assigned to the Coast Guard. Licensing and/or recertification requirements often demand continuing professional education, which enhances the practitioner's skills and professional credentials.
- b. The Office of Health and Safety attempts to fund one continuing education course annually for all licensed health services professionals. The program coordinator for an applicant's professional specialty must approve all training requests. Generally training should provide at least six documentable continuing education credits per day pertinent to the applicant's Coast Guard billet. Personnel should obtain training at the nearest possible geographic location.
- c. Medical and dental officers' licensing and certification exams will not be funded as continuing education. Coast Guard-sponsored Physician Assistant (PA) programs' graduates may request funding for examination fees (primary care only), travel to the testing site nearest their current duty station, and per diem associated with obtaining initial certification from the National Commission on Certification of Physician Assistants. The Coast Guard funds this one-time exception because it sponsors the PA training program and requires certification for employment. PAs may take the recertification examination in conjunction with the annual physician assistant conference. Travel and per diem will be authorized as annual CME. The member pays recertification examination fees.

- d. Except for Health Service Technician "C" School applicants, Health and Safety Program personnel requesting continuing education must follow these procedures:
 - (1) Each person requesting training must complete CG-5223, Short-Term Resident Training Request, with proper endorsements.
 - (2) Accompany each training request with course literature (e.g., a descriptive brochure) or a brief written description.
 - (3) Submit SF 182, Request, Authorization, Agreement and Certification of Training (10 parts) with proper endorsements if using a government purchase order to pay tuition or fees.
 - (4) Send all completed forms to Commandant (G-WKH) for processing. Send one information copy of the Short Term Training Request to the appropriate Maintenance and Logistics Command, Quality Assurance Branch.
 - (5) Training requests must arrive at Commandant (G-WKH) 8 weeks before the anticipated training convening date. Coast Guard Training Quota Management Center (TQC), Portsmouth, VA, processes approved requests and issues orders.

7. <u>Long-Term Training Programs</u>.

- a. Long-Term Post-graduate Training for Medical Officers (Physicians, Physician Assistants, and Nurse Practitioners). This 1- to 2-year program for medical officers principally emphasizes primary care (family practice, general internal medicine, and pediatrics). Consideration may be given for non-primary care specialties such as occupational health, public health, and preventive medicine. Training in orthopedics is a potential option for mid-level practitioners only. The Health Services Program Manager will consider non-primary care post-graduate medical training only when needed. Applicants also must have applied to their chosen training program and meet its requirements before requesting training. Applicants should have served with the Coast Guard Health Services Program for at least 2 years for each year of training received. For physician applicants, highest consideration will be given first to those who have not completed an initial medical residency. Commandant (G-WKH) has more information.
- b. Advanced Dental Training Programs. This 2-year program provides dental officers advanced training in general dentistry, enabling them to give more effective, comprehensive dental care to Coast Guard beneficiaries. The Department of the Navy, Naval Medical Command, Bethesda, MD, conducts the training, designed to qualify dental officers to meet the American Dental Association and Federal Services Board of General Dentistry requirements for specialty board examination. Dental officers chosen for this program are expected to pursue board certification. For program prerequisites and applications procedures, see the Coast Guard Training and Education Manual, COMDTINST M1500.1 (series).
- c. <u>Health Services Administration</u>. This program provides instruction in facility and personnel management, program planning, cost containment, quality assurance, third-party payment and liability, and medical-legal issues. The program provides

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training at the undergraduate (bachelor's degree) level for Chief Warrant Officers and senior enlisted HS personnel (Medical Administrators) and post-graduate (master's degree) level for officers in grades O-2, O-3, and O-4. See the Coast Guard Training and Education Manual, COMDTINST M1500.1 (series) for eligibility requirements, prerequisites, and application procedures.

d. Physician Assistant Program. Conducted at the U.S. Intra-service Physician Assistant Program, Fort Sam Houston TX, this program trains Coast Guard personnel interested in becoming Physician Assistants. Program graduates receive a baccalaureate degree from the University of Nebraska. If they meet eligibility requirements, graduates are offered a direct commissions as ensigns as described in the Personnel Manual, COMDTINST M1000.6 (series), Article 1.A.7. Each year three Coast Guard students are selected for training based on Service needs. Training at other institutions is not authorized. See the Coast Guard Training and Education Manual, COMDTINST M1500.1 (series) for eligibility requirements, prerequisites, and application procedures.

Section N - Patient Affairs Program

1. Patient Sensitivity.

- a. <u>The Coast Guard considers patient sensitivity issues of paramount importance</u> in delivering health care. Important issues in this area include medical record confidentiality, privacy during medical examination and treatment, respect for patient concerns, and enhancing the patient's perception of the quality of services delivered.
- b. All clinics shall conduct continuing patient sensitivity training. The "Treat Everyone As Myself" (TEAM) Program, developed by the U.S. Navy and Service Quality Institute available through each MLC Health and Safety Division, is the recommended course. It provides the structure for an internal review of patient-provider interaction and suggestions on ways to improve this relationship.

2. Patient Advisory Committee (PAC).

- a. The Coast Guard's health services program provides primary health care to a wide array of beneficiaries authorized by law and regulation. Medical Treatment Facilities (MTFs) often are unaware of their population's health problems until patients voice complaints or criticisms to the command. To enable beneficiaries to express their concerns, a PAC must be available to open lines of communication between health care providers and care recipients.
- b. Each Coast Guard MTF shall establish a PAC and specify criteria for committee functions. PACs shall include one officer and one enlisted member not assigned to the clinic; an active duty representative from each Coast Guard command in the clinic's service area; an active duty representative from each of the other uniformed services using the MTF; a retired representative; and an active duty dependent representative from both officer and enlisted communities.
- c. MTF shall conduct PAC meetings at least quarterly.
- d. The Chief, Health Services Division or his or her designee shall chair the meeting. Meeting minutes shall include recommended actions and an attendance list; and will be forwarded to the commanding officer with a copy to each PAC member. Specific PAC objectives include:
 - (1) Advise the Chief, Health Services Division on the range of services the beneficiary population requires;
 - (2) Serve as a communications link between the MTF and the beneficiaries the members represent;
 - (3) Serve as a patient advocacy group to assure all patients are accorded their rights as described in the Commandant's Patient Bill of Rights and Responsibilities;

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- (4) Assist the Chief, Health Services Division in advising patients of their responsibilities as described in the Commandant's Patient Bill of Rights and Responsibilities;
- (5) Assist the Chief, Health Services Division in establishing patient education programs; and
- (6) Advise the Chief, Health Services Division on the acceptability and convenience of the services provided.

3. Patient Satisfaction Assessment.

- a. <u>Assessing patient satisfaction through patient satisfaction surveys</u> has become an effective, efficient method to investigate and measure the quality of the Coast Guard health care delivery system from the patient's perspective.
- b. <u>A patient satisfaction survey form</u> shall be available to every patient who receives care at a Coast Guard facility.
- c. <u>Satisfaction surveys will be conducted annually</u> for all patient visits during a randomly selected one-week period.
- d. Locally prepared patient satisfaction surveys are authorized for use.
- e. <u>Patient satisfaction survey results shall be provided to the quality assurance focus</u> group for discussion and action and documented in meeting minutes. Survey results shall report and recommended actions to the unit commanding officer.
- f. <u>Persons distant from a Coast Guard clinic</u> can comment about care received from civilian providers by sending a mail-in Maintenance and Logistics Command survey form available from unit Health Services Technicians.

4. Patient Grievance Protocol.

- a. The Coast Guard expects health services personnel to maintain a professional attitude at all times. Our goal to provide the highest quality health care within allotted resources to all beneficiaries with the least personal inconvenience. Despite our best efforts, occasionally a patient will be dissatisfied with the care received.
- b. Whenever possible individuals with grievances should seek out or be referred to the clinic supervisor, health benefits advisor (HBA), or clinic administrator (CA) for complaint resolution before leaving the clinic. Refer written or telephone complaints to the appropriate clinic staff member. At a minimum, the complainant shall be given the name of his or her unit Patient Advisory Committee representative and advise the complainant of the time and place of the next PAC meeting.
- c. <u>If the clinic supervisor, HBA, or CA cannot resolve the complaint</u>, he or she shall refer the complainant to the senior medical or dental officer as appropriate.

- d. <u>Refer the complainant to the commanding officer</u> or higher authority only if the patient believes the clinic or PAC has not resolved the complaint.
- e. MLC (kqa) shall review concerns reported on forms mailed to the Maintenance and Logistics Command for quality assurance purposes, action, or referral to an appropriate level for resolution and follow up.

5. Congressional Inquiries.

- a. Occasionally, circumstances arise in which beneficiaries exercise their right to solicit assistance from their elected Congressional Representative to resolve their complaint with the Coast Guard health care system.
- b. <u>The Coast Guard maintains a Congressional liaison staff</u> to direct inquiries to the appropriate Headquarters office that can best address the issue and respond satisfactorily. Normally Commandant (G-WK) replies to health care problems.
- c. <u>Congressional inquiries require a complete investigation of the circumstances</u> surrounding the issues the beneficiary addresses. To this end, the command, health care facility, and individuals involved must supply supporting documentation and/or statements to assist in the investigation.
- 6. <u>Patient Bill of Rights and Responsibilities</u>. Each Coast Guard health care facility shall conspicuously display the Commandant's "Patient Bill of Rights and Responsibilities."

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